Exhibit RLS-1T

BEFORE THE WASHINGTON STATE
UTILITIES AND TRANSPORTATION COMMISSION

In Re Application of No. GA-079331 of SURE-WAY SYSTEMS, INC. For A Certificate of Public Convenience and Necessity to Operate Motor Vehicles in Furnishing Solid Waste Collection Service	DOCKET NO. TG-042089 **PREFILED TESTIMONY OF ROBERT L. SHERIDAN**

I, Robert L. Sheridan, subject to the penalties of perjury of the laws of the State of Washington, declare and state as follows:

Qualifications and Experience

1. I am knowledgeable and experienced with respect to the requirements of the federal Food, Drug, and Cosmetic Act (FDCA)[1] and the implementing regulations promulgated by the Food and Drug Administration (FDA)[2] applicable to medical devices.

2. I was employed by FDA from 1969 to 1992 in a series of increasingly responsible positions:

(a) From 1974 to 1976, I served as Director, Evaluation Staff, for the FDA's Bureau of Foods.

[1] 21 USC 301 et seq.
[2] 21 CFR Part H (Medical Devices).

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(b) From 1976 to 1980, I was Director, Program Planning and Evaluation Staff for the FDA's Bureau of Medical Devices.

(c) From 1980 to 1985, I was Director, Program Operations Staff, for the FDA's Office of Device Evaluation in the Center for Devices and Radiological Health (successor to the Bureau of Medical Devices).

(d) From 1985 to 1988, I was the Deputy Director of the FDA's Office of Device Evaluation.

(e) From 1988 to 1992, I served as the Director of the FDA's Office of Device Evaluation.

3. From 1976 to 1992, I dealt daily with the provisions of the FDCA and the FDA regulations applicable to medical devices. As Deputy Director and then Director of the FDA's Office of Device Evaluation from 1985 to 1992, I was responsible for all FDA programs to ensure the safety and effectiveness of medical devices clinically tested or marketed in the United States.

4. Since my retirement from FDA in 1992, I have worked as a consultant to the medical device industry on matters related to compliance with the requirements of the FDCA and FDA regulations governing medical devices. From 1992 through 2000, I was Senior Vice President for Device Evaluation with the consulting firm C. L. McIntosh & Associates, Inc., Rockville, Maryland. In 2001, I formed my own consulting firm under the name R. Sheridan Consulting, LLC, Wilmington, North Carolina, and continue consulting on medical device issues to the present. I am familiar with FDA's current medical device regulations.

5. I have a Bachelor of Arts degree in economics from Georgetown University (1965) and completed one and a half years of graduate study at George Washington University in business and public administration (1965-67) before entering the armed forces in 1967.

6. During my career with FDA, I received eight government meritorious service awards, including the highest awards available from both FDA and the Public Health Service. I

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have served as a member of the Editorial Review Board of the Medical Device and Diagnostic Industry magazine and as a member of the Food and Drug Law Institute's Medial Device Advisory Board. A list of publications I have authored since leaving FDA is attached as Exhibit RLS-16.

Overview of FDA Medical Device Regulation

7. Section 510 of the FDCA[3] sets out the core regulatory requirements applicable to persons engaged in the "manufacture, preparation, propagation, compounding, or processing" of any medical device -- activities that are usually referred to for convenience simply as "manufacturing."[4] Insofar as relevant here, a medical "device" is defined in the FDCA as "an instrument, apparatus, implement, machine, contrivance . . . or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals . . . ." Reusable sharps containers are considered accessories to hypodermic needles and are classified by FDA as Class II medical devices.

8. The most fundamental requirement of Section 510 is that a medical device manufacturer must register with the FDA. The first substantive provision of Section 510 -- Section 510(b)[5] -- provides that "every person who owns or operates any establishment . . . engaged in the manufacturing . . . of a . . . device or devices shall register" annually with FDA, identifying its name, place of business and all such establishments.[6] Section 510(c) provides

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[3] 21 USC 360.

[4] By regulation, the FDA has defined the terms "manufacture, preparation, propagation, compounding, or processing" to include "repackaging or otherwise changing the container, wrapper, or labeling of any device package," "[i]nitial importation of devices manufactured in foreign establishments" and "[i]nitiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating the specifications." See 21 CFR 807.3(d). Although the activities which subject a person to the requirements of Section 510 extend beyond what might ordinarily be considered "manufacturing," as is customary and for ease of communication I will use the terms "manufacture" and "manufacturer" herein to refer to all of those activities and persons subject to the requirements of Section 510 of the FDCA.

[5] Section 510(a) contains definitions.

[6] By its terms, the FDCA requires registration with the "Secretary" of the Department of Health and Human Services. However, these functions of the Secretary have been delegated to the FDA.

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that each new producer of medical devices "upon first engaging in the manufacture . . . of a . . . device or devices . . . shall immediately register" with FDA. The registration requirements of the FDCA are further supplemented by the FDA's regulations at 21 CFR Part 807.

9. Registration is the primary mechanism by which a manufacturer of medical devices comes to the attention of FDA and enters into the FDA's enforcement and inspection regime. Thus, Section 510(h) provides that "[e]very establishment . . . registered with the [FDA] pursuant to this section shall be subject to inspection . . . ." Section 510(h) further provides that "every such establishment engaged in the manufacture . . . of a . . . device or devices classified as class II or III shall be so inspected . . . at least once in the two-year period beginning with the date of registration . . . and at least once in every successive two-year period thereafter." Thus, the FDCA requires all device manufacturers to register with FDA and requires FDA to inspect all registered manufacturers.

10. Section 510(j) provides that persons required to register with FDA must also, at the time of registration, file a list of all medical devices manufactured for commercial distribution by such person and not previously listed with FDA. In combination, registration and listing pursuant to Section 510 bring the manufacturer and its products into the FDA's regulatory system, identifying both the manufacturer and its devices.

11. Section 301(p) of the FDCA defines "failure to register in accordance with [21 USC] section 360" as a "prohibited act." The FDCA further prohibits the distribution of a medical device that has not been listed with FDA or that was manufactured by an establishment that is not registered with FDA under Section 510. Such a device is "misbranded" under Section 502(o) of the FDCA[7] and the distribution of a misbranded device is prohibited by Section 301(a).[8]

[7] 21 USC 352(o).
[8] 21 USC 331(a).

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12. Section 510(k) provides that "[e]ach person who is required to register under this section" is also required to notify FDA and provide certain reports and information to FDA before introducing a medical device intended for human use into commerce. As provided in Section 513 of the FDCA[9] different classes of medical devices are subject to different "premarket" requirements before they can be distributed. Under Section 510(k), manufacturers of Class II medical devices must provide "premarket notification" of their intent to distribute the device but FDA "approval" of the device is neither required nor given. Only Class III medical devices must be approved by FDA. Class III devices are devices that pose an unreasonable risk or have critical functions related to the preservation or protection of human life and for which adequate information is not available to establish "special controls" adequate to ensure their safety and effectiveness. Class I and II medical devices are merely "cleared" for distribution by FDA upon submission of the required premarket notification and, in fact, FDA prohibits distributors of Class I or II devices from claiming that such devices have been "approved" by FDA. A representation that the device has been "approved" by FDA is considered false or misleading labeling. A device distributed in conjunction with such a misrepresentation is "misbranded" and its distribution is prohibited by Section 301(a).[10] 21 CFR 807.97 provides, "Any representation that creates the impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding."

13. Under Section 303(a)(1) of the FDCA,[11] a person who violates the prohibitions of Section 301 by failing to register when registration is required or by distributing a misbranded medical device is subject to criminal fine and imprisonment. In addition, Section 303(g),[12] provides that a person who distributes a misbranded medical device in violation of

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[9] 21 USC 360c.
[10] 21 USC 331(a).
[11] 21 USC 333(a)(1).
[12] 21 USC 333(g).

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Section 301 is liable to the United States for a civil penalty of up to $15,000 for each such violation or $1,000,000 for all such violations adjudicated in a single proceeding.

Requirements of the Food, Drug and Cosmetic Act and the FDA Regulations Applicable to Sure-Way Systems, Inc.

14. I have been asked to review whether Sure-Way Systems, Inc. ("Sure-Way") is in compliance with the requirements of the FDCA and the FDA's implementing regulations and, if not, to comment on the significance of its non-compliance within the FDA's regime for the regulation of medical devices. In doing so, I have reviewed and relied on the following materials, as well as my knowledge and experience with the FDA regulatory framework:

(a) FDA letter to Gary Chilcott, President of Sure-Way, dated December 16, 1999, responding to Sure-Way's premarket notification filings under Section 510(k) of the FDCA (copy attached as Exhibit RLS-2).

(b) Establishment Inspection Report issued by FDA with respect to an inspection of Sure-Way's Wilmington, CA sharps container processing facility conducted on January 10, 13 and 14, 2000 (copy attached as Exhibit RLS-3).

(c) Warning Letter issued by FDA, dated February 22, 2000, with respect to Sure-Way's Wilmington, CA processing plant (copy attached as Exhibit RLS-4).

(d) Warning Letter issued by FDA, dated February 10, 2000, to Carlos M. Campos, President & CEO of Safety Disposal System, Inc., West Palm Beach, FL (copy attached as Exhibit RLS-5).

(e) Warning Letter issued by FDA, dated March 7, 2001, to Carlos M. Campos, President & CEO of Safety Disposal System, Inc., West Palm Beach, FL (copy attached as Exhibit RLS-6).

(f) Initial Registration of Device Establishment, dated May 24, 2005, filed by Sure-Way with FDA on or about May 24, 2005, for its Butte, MT sharps container processing facility (copy attached as Exhibit RLS-7).

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(g) Initial Registration of Device Establishment, dated May 24, 2005, filed with FDA by Sure-Way for its Clearwater, FL sharps container processing facility, together with the FDA's letter dated June 15, 2005 confirming receipt of the registration on June 1, 2005 and notifying Sure-Way of the registration number issued by FDA for the Clearwater plant (copy attached as Exhibit RLS-8).

(h) Initial Registration of Device Establishment, dated May 24, 2005, filed with FDA by Sure-Way for its Valley City, ND sharps container processing facility (copy attached as Exhibit RLS-9).

(i) Initial Registration of Device Establishment, dated May 24, 2005, filed by Sure-Way with FDA for its Decatur, AL sharps container processing facility (copy attached as Exhibit RLS-10).

(j) Device Listing, dated May 24, 2005, filed by Sure-Way with FDA for the Sure-Way Systems, Inc. reusable sharps container (copy attached as Exhibit RLS-11).

(k) Sure-Way Systems, Inc. 510(k) Premarket Notification for Reusable Sharps Containers, August 1999, with cover letter and premarket notification checklist (Exhibit RLS-12).

(l) The FDA's Draft Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers, dated October 1993 (Exhibit RLS-13).

(m) Excepts from Sure-Way's QSR Manual (Revised 1/05/05) (Exhibit RLS-14).

(n) Sure-Way Sharps Disposal Service Contract (Exhibit RLS-15).

(o) The FDCA.

(p) The FDA's regulations at 21 CFR Subchapter H (Medical Devices).

15. Based upon my knowledge and experience and the materials identified in paragraph 14 above, it is my opinion that:

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(a) Sure-Way's reusable sharps containers are Class II medical devices. Sharps containers are classified as Class II medical devices because they are considered accessories to hypodermic needles. The FDA's Draft Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers, dated October 1993 (Exhibit RLS-13), identifies sharps containers as Class II devices. The FDA's 510(k) letter to Sure-Way dated December 16, 1999 (Exhibit RLS-2) explicitly notes that the Sure-Way Reusable Sharps Container is a Class II medical device. The Establishment Inspection Report issued by FDA for the inspection of Sure-Way's California processing plant in January 2000 (Exhibit RLS-3) identifies Sure-Way at p. 1 as a "Class II medical device manufacturer." The FDA internet web site identifies several companies that have listed reusable sharps containers with the FDA and indicates that all such listed devices have been categorized as Class II devices.

(b) Sure-Way is subject to regulation by FDA as a manufacturer of medical devices and is required to conform to Section 510 of the FDCA and the FDA's implementing regulations.

(i) Sure-Way submitted a premarket notification to FDA under Section 510(k) of the FDCA in 1999 (Exhibit RLS-12). See also the FDA's letter to Mr. Chilcott of December 16, 1999 (Exhibit RLS-2) providing premarket clearance. Only persons subject to Section 510, i.e., medical device "manufacturers," are required to submit a premarket notification under Section 510(k).[13] By filing a premarket notification under Section 510(k), Sure-Way conceded in 1999 that it is "a person required to register under [Section 510]." By the terms of Section 510(k), only "a person required to register" with FDA under Section 510 is required to file a premarket notification.

[13] For purposes of this discussion, I am omitting consideration of drug manufacturers, who are also subject to Section 510.

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(ii) The Establishment Inspection Report issued by FDA for the inspection of Sure-Way's California processing plant in January 2000 (Exhibit RLS-3) identifies Sure-Way at p. 1 as a "Class II medical device manufacturer." The FDA's Warning Letter to Sure-Way, dated February 22, 2000 (Exhibit RLS-4), states that Sure-Way "manufactures, reprocesses and distributes reusable sharps containers." These are official statements of the FDA's position concerning Sure-Way's activities. As official statements of the FDA's position on regulatory matters, FDA Warning Letters are published by FDA as guidance to other regulated entities and the public.

(iii) In addition to the official FDA statements issued to Sure-Way itself, identifying Sure-Way as a medical device manufacturer, FDA has determined that other firms that process sharps containers for reuse are manufacturers subject to Section 510 of the FDCA. Thus, in two Warning Letters issued to Safety Disposal System, Inc. on February 10, 2000 (Exhibit RLS-5) and March 7, 2001 (Exhibit RLS-6), FDA cited Safety Disposal for violations of the FDA's Quality System regulations at 21 CFR Part 820 applicable to "manufacturers" of medical devices. The February 10, 2000 Warning Letter at p. 2 cites issues with "your firm's manufacturing and quality assurance systems." The March 7, 2001 Warning Letter states clearly at p. 1 that "the product(s) that your firm manufactures/reprocesses" are medical devices subject to the Quality System regulations at 21 CFR Part 820. 21 CFR Part 820 "establishes basic requirements applicable to manufacturers of finished medical devices." 21 CFR 820.1(a)(1).

(iv) In late May 2005, Sure-Way registered its processing plants in Montana, North Dakota, Alabama and Florida with FDA and listed its reusable sharps containers with FDA pursuant to Section 510 of the FDCA. Only medical device (and drug) manufacturers are required to register under Section 510 (see Section 510(b) and (c)) and the device listing requirement applies only to persons subject to the registration requirement (see Section 510(j)).

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(v) Sure-Way's May 2005 Initial Registration filings with FDA dated May 24, 2005 (Exhibits RLS-7 through RLS-10) identify Sure-Way as a "specification developer." The FDA's regulations define "manufacturer" to include a "specification developer." 21 CFR 807.3(d) provides that the terms "[m]anufacture, preparation, propagation, compounding, assembly, or processing of a device . . . include the following activities: . . . (3) Initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating the specifications." The FDA's Quality System Regulation, 21 CFR Part 820, defines "manufacturer" to include "those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development." 21 CFR 820.3(o). Within the FDA regulatory regime, a "specification developer" is a "manufacturer," subject to all of the requirements of Section 510.

(c) Sure-Way's operations violated the FDCA and the FDA's implementing regulations prior to May 24, 2005. Sure-Way did not register as a medical device manufacturer or list its medical devices with FDA, as required by Section 510(b), (c) and (j), until May 24, 2005. Sure-Way's prior failure to register violated Section 301(p) of the FDCA.[14] Sure-Way's distribution of its reusable sharps containers prior to May 24, 2005 constituted the distribution of a misbranded device in violation of Section 301(a) and (b).[15] Sure-Way is liable for both criminal and civil penalties as a result of these violations.

(d) Sure-Way's failure to register with FDA as a manufacturer of medical devices allowed Sure-Way to evade FDA inspection of its manufacturing operations.

(i) As noted above and as provided by Section 510(h), the FDA's inspection regime is tied to registration. Registration is the means by which FDA identifies the "establishments" or manufacturing locations where manufacturing operations are conducted. A 510(k) premarket notification will generally identify the manufacturer, but this information is

[14] 21 USC 331(p).
[15] 21 USC 331(a), (b).

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not put into a database to schedule inspections. That is the function of registration. Registration is also the step that starts the clock running on the FDA's inspection program. If Sure-Way had registered with FDA at the time it filed its 510(k) premarket notification, the FDA would have inspected Sure-Way's operations several times prior to the present date -- perhaps as often as three times if resources allowed FDA to meet its biennial inspection obligations under Section 510(h) of the FDCA.

(ii) Although FDA in fact inspected Sure-Way's California facility in 2000, this inspection apparently resulted from the accidental discovery of Sure-Way's processing operations during the inspection of another company at the same location. The Establishment Inspection Report issued by FDA for the Sure-Way inspection in January 2000 (Exhibit RLS-3) states at p. 1 that "The inspection of Sure-Way Systems, Inc. was not pre-announced because the firm was discovered during an inspection of Amaritime Environmental Solutions, Inc." The Inspection Report notes that Sure-Way's California plant was not then registered with FDA but focuses on flaws in Sure-Way's processing policies, practices, systems and methods.[16] Sure-Way's failure to register with FDA has apparently allowed Sure-Way to evade FDA inspections of its Butte, Montana plant. So far as I am aware, none of Sure-Way's existing plants has ever been inspected by FDA.

(e) Because Sure-Way has evaded inspection of its existing processing plants by failing to register those plants with FDA until May 2005, it is unknown whether the operations conducted by Sure-Way at any of its processing plants are in compliance with the requirements of the FDA's Quality System Regulation, 21 CFR Part 820. Absent FDA inspection, there can be no assurance that Sure-Way's processing operations are being conducted in compliance with the FDCA or the FDA's regulations. The FDA inspection in 2000 found substantial violations. Since Sure-Way has evaded inspection of its existing plants by failing to register, compliance

[16] It may be that Sure-Way advised the FDA inspector that its registration was "pending," as Sure-Way advised the FDA in its 510(k) submission. See discussion below.

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with the FDCA and the FDA's regulations cannot and should not be assumed.

(f) Sure-Way's reusable sharps containers are misbranded in violation of Section 502(a)[17] because Sure-Way has falsely represented that its reusable sharps containers have been "approved" by FDA. Sure-Way's "Sharps Disposal Contract" (Exhibit RLS-15) states at section 1.1 that Sure-Way provides "510K FDA and DOT approved reusable sharps containers" to its customers. Review of a premarket notification for a Class II medical device does not result in FDA "approval" of the device. The FDA's regulations at 21 CFR 807.97 state: "Any representation that creates the impression of official approval of a device because of complying with the premarket notification regulations [under Section 510(k)] is misleading and constitutes misbranding." Sure-Way's misrepresentation that its sharps containers have been "approved" by FDA in materials furnished to its customers renders the containers misbranded. Distribution of a misbranded device is prohibited by Section 301(a).[18] Sure-Way is therefore subject to the criminal and civil penalties prescribed by Section 303 of the FDCA[19] for this violation as well as the others noted above.

(g) Sure-Way's failure to register its plants with FDA prior to May 2005 and misrepresentation that its sharps containers have been "approved" by the FDA show a disregard for its regulatory obligations.

(i) Sure-Way has acknowledged that the primary agency that regulates its reusable sharps processing operations is the FDA. Sure-Way's QSR Manual (1/05/05 revision) states:

> [T]he activity of returning sharps containers to service [after use] is regulated by the U.S. Food and Drug Administration . . . . The FDA defines Sure-Way System's sharps container reprocessing work as a "remanufacturing" activity, because each cycle of container emptying, disinfection and reassembly prepares the previously used sharps container for service as if it were new and being used for the first time. As a manufacturing process, 21 CFR Part 820 requires that Sure-Way System's sharps container reprocessing activities be performed in

[17] 21 USC 352(a).
[18] 21 USC 331(a).
[19] 21 USC 333.

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> accordance with current "good manufacturing practices" (GMP) more fully detailed under the Quality System Regulations (QSR) of Part 820 of Title 21 of the Code of Federal Regulations (CFR) to ensure that the containers are safe and effective for their intended use.

Exhibit RLS-14 at p. 5. "The primary agency which regulates our business is the Food and Drug Administration (FDA)." Id. at p. 36. Sure-Way's QSR Manual is a restatement of the requirements of the FDA's Quality System Regulation ("QSR"), 21 CFR Part 820, applicable to "manufacturers" required to register under Section 510(b) and (c). Thus, while acknowledging that FDA is the primary agency responsible for regulating its business, Sure-Way disregarded or remained ignorant until May 2005 of its most basic obligation under the regulatory regime administered by FDA -- the obligation to register.

(ii) As noted above, by the express terms of Section 510(k), the premarket notification requirement applies only to persons also "required to register" under Section 510(b) and (c). Sure-Way provided the premarket notification required by Section 510(k) but did not register as required by Section 510(b) or (c). If this was not the result of a deliberate decision to disregard the registration requirement, it could only have occurred as a result of the failure of responsible Sure-Way management personnel to read Section 510, including Section 510(k), notwithstanding that Sure-Way believed itself subject to Section 510.

(iii) The establishment registration and device listing requirements of the FDCA are prominently described in the FDA's regulations at 21 CFR Part 807. In addition, the registration requirement was flagged for Sure-Way by the FDA's premarket notification rule, 21 CFR Part 807, Subpart E, and by FDA's Draft Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers (October 1993) (Exhibit RLS-13). 21 CFR 807.87(b) provides that "[e]ach premarket notification submission shall contain . . . [t]he establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission." The Draft Guidance directs that the "cover letter" for the 510(k) submission should include the submitter's registration number. See

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Exhibit RLS-13, Section D, Item 7. Sure-Way's August 1999 510(k) submission (Exhibit RLS-12) states at p. 1 that the information contained in the submission "is provided as required by 21 C.F.R. § 807.87 and FDA's 'Draft 510(k) Guidance on Sharps Containers' (October 1993)." Sure-Way's 510(k) submission then states that "the establishment registration numbers" for the device's manufacturer (identified as L & H Molds and Engineering) and distributor (identified as Sure-Way) are "pending." Exhibit RLS-12 at p. 1. Thus, both the FDA's 510(k) rule and Draft 510(k) Guidance on Sharps Containers put Sure-Way on notice of Section 510's registration requirements. Sure-Way was forced to confront the issue of registration in preparing its 510(k) submission and represented to FDA that its registration was "pending."

(iv) The FDA's December 16, 1999 510(k) letter to Gary Chilcott of Sure-Way (Exhibit RLS-2) states, "You may, therefore market the device, subject to the general controls provisions of the FDCA. The general controls provisions of the FDCA include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration." The FDA gave Mr. Chilcott explicit notice of the FDCA's registration and listing requirements in this letter.

(v) Sure-Way's disregard for its obligations under the FDCA can only be described as blatant. Only after it became clear that these compliance issues would be involved in this proceeding did Sure-Way register its plants and list its devices. If Sure-Way's failure to register with FDA prior to May 24, 2005 was not a knowing and deliberate attempt to evade registration and inspection, ignorance of the registration requirement in the circumstances described above is a species of willful ignorance that shows a serious disregard for Sure-Way's regulatory compliance obligations, an unusual degree of incompetence or both. In any event, Sure-Way's track record on compliance with the FDCA and the FDA's regulations raises a significant question about whether Sure-Way can be relied upon to meet its regulatory obligations in the future.

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DATED this 15th day of July, 2005.

Robert L. Sheridan

Robert L. Sheridan

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Exhibit RLS-2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 1999

Mr. Gary Chilcott, President
Sure-Way Systems, Incorporated
310 East Harry Bridges Boulevard
Wilmington, California 90744

Re: K992626
Trade Name: Sure-Way Reusable Sharps Container
Regulatory Class: II
Product Code: FMI
Dated: October 7, 1999
Received: October 25, 1999

Dear Mr. Chilcott:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6-1

Indications for Use Statement
Revised 11/10/99

Ver/ 3 - 4/24/96

Applicant: Sure-Way Systems, Inc.

510(k) Number (if known): K992626

Device Name: Sharps Container

Indications For Use:

The Sure-Way Reusable Container is intended to be used for the disposal of contaminated medical sharps in health care facilities.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992626

Exhibit RLS-3

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ESTABLISHMENT INSPECTION REPORT **PAGE 1**

Sure-Way Systems, Inc.
310 E. Harry Bridges Blvd.
Wilmington, CA 90744
FEI: 3002911426
1/10, 13 & 14/2000 KC (924)

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SUMMARY OF FINDINGS:

This was a directed Quality System (QS) inspection of a small Class II medical device manufacturer and reprocessor of reusable sharps containers per assignment 000393 from Division of Enforcement II, Office of Compliance, CDRH, HFZ-333. The sharps containers manufactured and reprocessed by the firm are not subject to Medical Device Tracking regulations. This inspection was conducted in accordance with the Compliance Program 7382.845 – Inspection of Medical Devices. Medical Device Profile Class – PRF was covered.

This initial inspection of Sure-Way Systems, Inc. focused on the cleaning of reusable sharps containers that are returned by hospitals or laboratories after use. The inspection revealed the firm was not operating in a state of control for the reprocessing operation of sharps containers. Objectionable conditions noted on the Inspectional Observations, FDA 483, included:

1) No quality policy, quality plan and quality audit procedures;
2) No validation study for the sharps container cleaning process;
3) No written procedures for design control, change controls, cleaning process, complaints and MDRs;
4) No written acceptance criteria for incoming and finished products; and
5) No Device History Records.

A twelve-item FDA 483 was issued to the firm's management. They promised to make corrections to all observations of objectionable conditions and to respond in writing to the Los Angeles District Office by 2/15/2000.

HISTORY OF BUSINESS:

Sure-Way Systems, Inc. has been a privately held Montana Corporation since 1983. The firm is a major medical waste hauler in Montana and Wyoming. It collects medical wastes from hospitals and laboratories and processes them to municipal solid waste. The firm's headquarters office is located at 4072 Eastside Road, Stevensville, Montana 59870. The majority shareholders and Corporate Officers are:

Mr. Gary Chilcott – President.
Mr. William Lawrence – Vice President and Director.
Mrs. Dawn Chilcott – Treasure of the Boards of Directors (Wife of Mr. Gary Chilcott).

Sure-Way Systems, Inc.
310 E. Harry Bridges Blvd.
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The firm started the reprocessing business of sharps containers after moving into the Amaritime facility in Wilmington in late 1998. The firm was previously located at 2472 Chambers Road, Suite 250, Tustin, CA 92780. Amaritime Environmental Solutions, Inc. is a medical waste hauler. Sure-Way Systems, Inc. at this Wilmington facility has only [redacted] full time employees and its normal operational hours are from 8:00 a.m. – 4:30 p.m., Monday through Friday.

This firm is currently not registered with the FDA. All FDA correspondence should be addressed to Mr. Gary Chilcott - President of Sure-Way Systems, Inc. at 310 Harry Bridges Blvd., Wilmington, CA 90744. The firm has obtained their first 510(k), #K992626, from the FDA for reusable sharps containers in December 1999. It plans to replace their existing ones manufactured by [redacted] with the new design starting in March 2000.

Exhibit #1 is an interstate shipping record for a shipment of [redacted] reusable sharps containers. It includes a Purchase Order and a Packing List showing that 1625 units of 2-Gallon [redacted] reusable sharps container were picked up from [redacted] on 4/21/97 and shipped to Sure-Way System, Inc. in Montana. Sure-Way Systems, Inc. reprocesses [redacted] sharps containers.

PERSON INTERVIEWED AND RESPONSIBILITIES:

The inspection of Sure-Way Systems, Inc. was not pre-announced because the firm was discovered during the inspection of Amaritime Environmental Solutions, Inc. Both Amaritime Environmental Solutions, Inc. and Sure-Way Systems, Inc. are listed on the inspection assignment from HFZ-333.

One 1/10/2000, I displayed my Credentials and issued a Notice of Inspection to Mr. Bruce H. Collins, Professional Engineer and Director. Mr. Collins was the most responsible person at the firm during the issuance of the Notice of Inspection. He accompanied me during the walk-through of the facility and provided me with information on the cleaning process of sharps containers before Mr. Chilcott returned from the field. He reports to Mr. Chilcott.

I met with Mr. Chilcott at the end of the facility walk-through on 1/10/2000. I briefed him on the purpose of my inspection and he accompanied me during the rest of the inspection. He provided me with most of the information for this report. He is the most responsible person and also one of the majority shareholders in the firm. He reports to the Board of Directors.

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Individuals at the firm participating in the inspection included:
Mr. Don Terwiske – President of Amaritime Environmental Solutions, Inc., introduced me to Mr. Collins on 1/10/00. He provided information regarding the relationship between Amaritime and Sure-Way. Mr. Terwiske is a business partner with Mr. Chilcott and also an investor of Sure-Way sharp containers business.

Mr. Patrick B. Osborn – Director of Engineering was present on the last two days of the inspection. He was involved in the design of the new sharps containers submitted to the FDA for the 510(k) Premarket Notification in 1999. He answered questions regarding the new sharps containers as well as the quality system procedures. He reports to Mr. Chilcott.

OPERATIONS:

[redacted]he firm has obtained a 510(k) for sharps containers in December 1999 and plans to replace their existing sharps containers, purchased fro[redacted]n 1997, with the new ones starting in March 2000. Exhibit #2 is a typical contract, Sharps Disposal Service Program, signed by a medical facility with Sure-Wa[redacted]

[redacted] The firm is supposed to follow the cleaning process required by Section 118295 of the California Medical Waste Management Act, exhibit #3 for reusable rigid containers for medical waste. [redacted]

[redacted] Exhibit #4 is a product label used on a reusable sharps container.

Personnel who may come in contact with a contaminated device are required by the firm to have the training for blood borne pathogens. Supervisors are reportedly always on site since the firm operates only on day shift.

OBJECTIONABLE CONDITIONS & DISCUSSION WITH MANAGEMENT:

At the conclusion of the inspection on 1/14/2000, a two page Inspectional Observations, FDA-483, was issued to Mr. Gary Chilcott, President of Sure-Way Systems, Inc. Also present in the discussion was Mr. Patrick B. Osborn. Prior to the FDA-483 discussion, I provided Mr. Chilcott a Resources for FDA Regulated Businesses and a "Medical Device Inspection Evaluation" package and told him to read the enclosed letter in the package and to return the survey form in the pre-stamped envelope to University of California, Irvine.

I explained that this list represents my observations of objectionable conditions made during the inspection and that these conditions may be determined, after review by the Compliance Branch, to be violations of the Federal Food, Drug and Cosmetic Act. I read each observation listed below aloud and provided the firm an opportunity for discussion after each observation.

1. The firm has not established a quality policy, a quality plan and quality audit procedures.

Mr. Chilcott was not aware that the firm's reprocessing operation of sharps containers are subject to the FDA Quality System Regulations. As a result, the firm does not have any written procedures required by the QS Regulations.

Annotation: Correction promised by 2/15/2000.

Discussion: Mr. Chilcott agreed with the observation and promised to establish a quality policy, a quality plan and quality audit procedures.

2. Document control and design change control procedures have not been established.

My review of the 510(k) submission for sharps containers revealed the firm did not maintain a design history file. Design changes were not documented during the development of the sharp containers. Mr. Osborn stated whenever there was a change in specification, he would discuss it with the appropriate people, but the change was not formally documented. He also stated the firm did not have any procedures for document and design change controls.

Annotation: Correction promised by 2/15/2000.

Discussion: Both Mr. Chilcott and Mr. Osborn agreed with the observation. They promised to establish written procedures for document and design change controls.

3. Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been established. Specifically, the firm has no written specifications on chemicals used in th[redacted] washer for sanitizing reusable sharps containers.

During the walk-through of the facility with Mr. Collins on 1/10/00, I noticed that the firm was using the[redacted] and[redacted]9 chemicals for washing sharps containe[redacted] maintains the[redacted] washer for Sure-Way and supplies both chemicals. When I was with Mr. Chilcott on 1/13/00, I found th[redacted] was replaced w[redacted]sked Mr. Chilcott what the difference between th[redacted] and[redacted] nd he said both chemicals contain [redacted]olution that is required by Section 118295 of the California Medical Waste Management Act. Mr. Chilcott could not provide me any written specifications for the cleaning solutions.

Annotation: Correction promised by 2/15/2000.

Discussion: Mr. Chilcott stated that this would be good business practice to establish written specifications for the cleaning chemicals. Mr. Osborn promised to correct it by 2/15/2000.

4. The cleaning process for reusable sharp containers and transport carts has not been validated.

The firm has not performed any validation study to ensure that the use[redacted]sher, the cleaning chemicals and its operating parameters are effective to remove bioburden from used sharps

containers. The [redacted]asher is often used as a small dish washing machine in restaurants.

Annotation: Correction promised by 3/1/2000.

Discussion: Mr. Chilcott asked me what kind of tests are required to validate the cleaning process. I told him that the firm should determine the bioburden levels for returned sharps containers before and after the cleaning operation. I also suggested that the firm should develop a validation protocol and document all testing results in a validation report. Mr. Osborn stated that they might perform swab tests on returned sharps containers and transport carts in the validation.

5. Process control procedures for cleaning reusable sharps containers have not been established. Specifically, the firm has no written operating procedures and specifications for the [redacted] washer.

Since the firm has no written operating procedures and specifications for the [redacted]asher, the operating parameters including the amount of chemical used, the dwell time and the temperature of the hot water may have been changed after each service performed by different technicians from [redacted]e firm contract[redacted]maintain[redacted]asher.

6. Equipment used in the washing and decontamination process for reusable sharp containers does not meet specified requirements. Specifically, the temperature of the water used in th[redacted] washer is only [redacted]stead of [redacted]egrees Fahrenheit and the exposure to the chemical sanitizer is approximately [redacted]ead of three minutes as required by Section 118295 of the Medical Waste Management Act.

During the inspection, Mr. Collins stated the firm follows Section 118295 of the California Medical Waste Management Act using the chemical sanitizer to wash reusable sharps containers instead of hot water because the firm's boiler cannot generate hot water reaching 180 degrees Fahrenheit. During a demonstration performed by Mr. Chilcott, I noticed the complete cycle used for washing a sharp container was less than one minute and the temperature gage of th[redacted]vasher was read betwee[redacted]egrees Fahrenheit. Section 118295 of the Medical Waste Management Act requires a reusable container be exposed to hot water of at least 180 degree Fahrenheit for a minimum of 15 seconds or chemical sanitizer for a minimum of three minutes.

Annotation: Correction promised by 3/1/2000.

Discussion: Mr. Chilcott was aware that [redacted]sher was not meeting the State requirements. He stated the firm has purchased a new washer that would meet the requirements and would have it installed by 3/1/2000.

7. Schedules for the adjustment, cleaning and other maintenance of equipment have not been established. Specifically, the firm has no maintenance schedule and records for the [redacted] washer and the automated lid remover.

Mr. Chilcott could not provide any maintenance and service records for th[redacted]asher when I requested for them during the inspection. In fact, the firm did not establish any maintenance and cleaning schedules for th[redacted]asher. In addition, the automated lid remover is installed with a Hepa filter and the firm had no records on the filter replacement.

Annotation: Correction promised by 3/1/2000.

Correction: Mr. Osborn promised to develop a maintenance log for bot[redacted]asher as well as the automated lid remover and to keep all maintenance records in the future.

8. The firm has not established receiving, in-process and finished device acceptance procedures.

At the time of the inspection, the firm did not have any written procedures including a sampling plan for inspecting chemical solutions and washed sharps containers.

Annotation: Correction promised by 3/15/2000.

Correction: Mr. Osborn stated the firm would establish written procedures for receiving, in-process and finished device acceptance.

9. The firm has no Device History Records for reprocessing sharp containers. Specifically, the dates of reprocess, the quantity re-processed, the quantity released for distribution and the acceptance records.

At the time of the inspection, the firm only had records for the numbers of container and the amount

of medical waste received from hospitals, but the processing records including the dates of reprocess, the quantity re-processed, the quality released for distribution and the acceptance records were not documented.

Annotation: Correction promised by 2/15/2000.

Discussion: Mr. Osborn agreed with the observation and promised to establish Device History Records to document the re-processing by 2/15/00.

10. The firm has no complaint handling procedure and Medical Device Reporting (MDR) procedure.

Mr. Chilcott was not aware of the MDR regulation. During an interview with Mr. Keith Edward, he explained that in case there was a product complaint, a service technician would document it in a Daily Report, exhibit #5. The firm did not have a written procedure to describe what a product complaint is and the necessary steps to follow when there is a product complaint. Mr. Edward stated the firm has not received any complaints since the firm started the reprocessing of sharps containers in late 1998. Mr. Edward could not provide me the file containing the Daily Reports when I asked to review them. He said the firm did not keep them.

Annotation: Correction promised by 2/15/2000.

Correction: Mr. Chilcott promised to have the complaint and MDR procedures by 2/15/2000.

11. Procedures for identifying product throughout all stages of incoming, production and distribution are not defined. Specifically, the acceptance status of product and areas of operation are not identified.

During the walk-through of the facility, I noticed that neither the areas of operation nor the acceptance status of products including the transport carts were identified. Since the firm's operation is in a warehouse and there is no wall separating each operation, there is a possibility that someone may accidentally use a contaminated transport cart for stocking cleaned sharps containers.

Annotation: Correction promised by 3/15/2000.

Correction: Mr. Osborn agreed to establish written procedures and to identify the areas of operation

in the facility when the firm has completed the installation of the new washer.

12. Procedures have not been defined to prevent contamination of product by certain substances. Specifically, washed sharp containers were placed upside down directly on wet floor contaminated with washing solution from a washer sanitizing reusable medical waste containers.

During the walk-through of the facility, I observed some washed sharps containers were contaminated with washing solution from a washer sanitizing reusable medical waste containers. The washed sharp containers were placed upside down directly on wet floor instead of on a rack. On 1/13/00, I verified the firm had made a voluntary correction by placing washed sharp containers on a rack.

Annotation: Correction promised by 3/15/2000.

Correction: Mr. Osborn stated written procedures would be established once the new washer was installed.

At the end of the inspection, I provided a copy of the Quality System Regulation, CFR 21 Part 820 to Mr. Chilcott for his information. He reiterated his commitment to comply and promised to respond in writing with corrective actions to the Los Angeles District by 2/15/00.

ATTACHMENTS:

1) Notice of Inspection, FDA-482 dated 1/10/00.
2) Inspectional Observations, FDA-483 dated 1/14/00.
3) Assignment 000393 from Division of Enforcement II, Office of Compliance, CDRH, HFZ-333.

EXHIBITS:

1) An interstate shipping record for a shipment o[redacted]eusable sharps containers.
2) A typical contract, Sharps Disposal Service Program, signed by a medical facility with Sure-Way.
3) Section 118295 of the California Medical Waste Management Act for reusable rigid containers for medical waste.

4) A product label used on a reusable sharps container.
5) A Daily Report.

Kelvin Cheung

Kelvin Cheung
Engineer
LOS-DO/CPK-RP

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS AND PHONE NUMBER 19900 MacArthur Blvd. #300 Irvine, CA 92612 (949) 798-7600	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Mr. Gary Chilcott	PERIOD OF INSPECTION 1/10, 13 & 14/2000	C.F. NUMBER
TITLE OF INDIVIDUAL President	TYPE ESTABLISHMENT INSPECTED Medical device reprocessor & manufacturer	ice 1/14/2000
FIRM NAME Sure-Way Systems, Inc.	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same	
STREET ADDRESS 310 E. Harry Bridges Blvd.	STREET ADDRESS OF PREMISES INSPECTED Same	
CITY AND STATE (Zip Code) Wilmington, CA 90744	CITY AND STATE (Zip Code) Same	
DURING AN INSPECTION OF YOUR FIRM I OBSERVED:		

THE OBSERVATIONS NOTED ON THIS FDA483 ARE NOT AN EXHAUSTIVE LISTING OF OBJECTIONABLE CONDUCTIONS. UNDER THE LAW, YOUR FIRM IS RESPONSIBLE FOR CONDUCTING INTERNAL SELF AUDITS TO IDENTIFY AND CORRECT ANY AND ALL VIOLATIONS OF THE GMP REGULATIONS.

1. The firm has not established a quality policy, a quality plan and quality audit procedures.

2. Document control and design change control procedures have not been established. Correction promised by 2/15/2000.

3. Procedures to ensure that all purchased or otherwise received product and services confirm to specified requirements have not been established. Specifically, the firm has no written specifications on chemicals used in th[redacted]washer for sanitizing reusable sharps containers. Correction promised by 2/15/2000.

4. The cleaning process for reusable sharp containers and transport carts has not been validated. Correction promised by 2/15/2000

5. Process control procedures for cleaning reusable sharps containers have not been established. Specifically, the firm has no written operating procedures and specifications for th[redacted]asher. Correction promised by 3/1/2000

6. Equipment used in the washing and decontamination process for reusable sharp containers does not meet specified requirements. Specifically, the temperature of the water used in th[redacted]asher is only [redacted]nstead o[redacted]egrees Fahrenheit and the exposure to the chemical sanitizer is approximatel[redacted]nute instead of three minutes as required by Section 118295 of the Medical Waste Management Act. Correction promised by 3/1/2000

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kelvin Cheung	EMPLOYEE(S) NAME AND TITLE (Print or Type) Kelvin Cheung, Engineer	DATE ISSUED 1/14/2000

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS AND PHONE NUMBER 19900 MacArthur Blvd. #300 Irvine, CA 92612 (949).798-7600	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Mr. Gary Chilcott	PERIOD OF INSPECTION 1/10, 13 & 14/2000	C.F. NUMBER
TITLE OF INDIVIDUAL President	TYPE ESTABLISHMENT INSPECTED Medical device reprocessor & Manufacturer	
FIRM NAME Sure-Way Systems, Inc.	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same	
STREET ADDRESS 310 E. Harry Bridges Blvd.	STREET ADDRESS OF PREMISES INSPECTED Same	
CITY AND STATE (Zip Code) Wilmington, CA 90744	CITY AND STATE (Zip Code) Same	

7. Schedules for the adjustment, cleaning and other maintenance of equipment have not been established. Specifically, the firm has no maintenance schedule and records for th[redacted]vasher and the automated lid remover. Correction promised by 3/1/2000

8. The firm has not established receiving, in-process and finished device acceptance procedures. Correction promised by 3/15/2000

9. The firm has no Device History Records for reprocessing sharp containers. Specifically, the dates of reprocess, the quantity re-processed, the quantity released for distribution and the acceptance records. Correction promised by 2/15/2000

10. The firm has no complaint handling procedure and Medical Device Reporting (MDR) procedure. Correction promised by 2/15/2000

11. Procedures for identifying product throughout all stages of incoming, production and distribution are not defined. Specifically, the acceptance status of product and areas of operation are not identified. Correction promised by 3/15/2000

12. Procedures have not been defined to prevent contamination of product by certain substances. Specifically, washed sharp containers were placed upside down directly on wet floor contaminated with washing solution from a washer sanitizing reusable medical waste containers. Correction promised 3/15/2000

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kelvin Cheung	EMPLOYEE(S) NAME AND TITLE (Print or Type) Kelvin Cheung, Engineer	DATE ISSUED 1/14/2000

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NO.
19900 MacArthur Blvd. #300
Irvine, CA 92612
(949) 798-7600

TO

2. NAME AND TITLE OF INDIVIDUAL
Mr. Bruce H. Collins

3. DATE
1/10/00

4. FIRM NAME
Sure-Way Systems, Inc.

5. HOUR
~~4:44~~ a.m.
1:40 p.m.

6. NUMBER AND STREET
310 E. Harry Bridges Blvd.,

7. CITY AND STATE & ZIP CODE
Wilmington, CA 90744

8. PHONE # & AREA CODE
(310)522-0150

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

9. SIGNATURE *(Food and Drug Administration Employee(s))*
Kelvin Cheung

10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))*
Kelvin Cheung, Engineer

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec.704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein *(including records, files, papers, processes, controls, and facilities)* bearing on whether prescription drugs or restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data *(other than data as to qualifications of technical and professional personnel performing functions subject to this Act)*, and research data *(other than data relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 507(d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the title)*. **A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.**

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F - Licensing - Biological Products and Clinical Laboratories
and******

Sec. 351(c) "Any officer, agent, or employee of the Department of Health & Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - ******Control of Radiation.

Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests *(or testing programs)* required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records *(including testing records)*, make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

******

(f) "The Secretary may by regulation (1) require dealers and disbributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information.

(Continued on Reverse)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

MAR 6 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gary Chilcott, President
Sure-Way Systems, Inc.
310 East Harry Bridges Boulevard
Wilmington, CA 90744

Dear Mr. Chilcott:

We have completed our review of your letter dated February 22, 2000, which you provided in response to the form FDA 483 which was issued to you on January 14, 2000. We find that your response adequately addresses our concerns which were stated in the Warning Letter and FDA 483, and therefore the approval of any pending premarket submissions, or Export Certificates for products manufactured at your facility will not be deferred due to GMP issues. This information will be made available for reference by Federal agencies when considering award of contracts.

Sincerely,

James E. Kozick
Acting District Director

SURE-WAY SYSTEMS, INC.
310 E. Harry Bridges Blvd.
Wilmington, CA 90744
(310) 522 0150

Feb. 22, 2000

District Director
Department of Health and Human Services
U.S. Public Health Services
Food and Drug Administration
19900 MacArthur Blvd. #300
Irvine CA, 92612

Attention: Kelvin Cheung

Subject: Response to FDA 483 Inspection Report of Jan. 14, 2000

Gentlemen:

We are submitting herewith our response to the subject inspection report. We have addressed each issue mentioned in the report, in the order in which they are presented.

It is also noteworthy to advise that, since the date of the inspection, we have installed and are using the new [redacted] container tipper and washing equipment. We have discontinued our interim use of the [redacted] washer. The new washer is operating in compliance with Section 118295 of the State Medical Waste Management Act.

We will be pleased to demonstrate the operation of the new equipment, at your convenience.

Very truly yours,

Gary Chilcott

Gary Chilcott
President

Exhibit RLS-4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
HFZ-35 M3430

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

FEB 2 2 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gary Chilcott, President
Sure-Way Systems, Inc.
310 E. Harry Bridges Boulevard
Wilmington, CA 90744

W/L 29-00

Dear Mr. Chilcott:

During an inspection of your facility conducted on January 10, 13 and 14, 2000, our investigator determined that your firm manufactures, reprocesses and distributes reusable sharps containers. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and implement a quality policy which defines the intentions and direction of your organization with respect to quality [21 CFR 820.20(a)].

2. Failure to establish and implement a quality plan which defines the quality practices, resources, and activities relevant to devices designed and manufactured by your firm [21 CFR 820.20(d)].

3. Failure to establish and implement procedures for a systematic, independent examination of your quality system at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with the quality system procedures [21 CFR 820.22].

4. Failure to establish and implement procedures to control the design of your device in order to ensure that specified design requirements are met [21 CFR 820.30(a)].

5. Failure to establish and implement procedures to control all documents required by the Quality System Regulation [21 CFR 820.40].

6. Failure to establish and implement procedures to ensure that all purchased or otherwise received product and services conform to specified requirements [21 CFR 820.50].

7. Failure to develop, conduct, control, and monitor production processes to ensure your devices conform to their specifications [21 CFR 820.70 & 75]. Specifically, your firm has no documented evidence which provides a high degree of assurance that your cleaning processes for your reusable devices used as part of production meet their pre-determined specifications and quality attributes. Most disturbing is that our investigation disclosed instances where equipment used in the washing decontamination process for reusable sharp containers did not meet their specified requirements and no investigations were conducted. Additionally, your firm has no schedules for the adjustment, cleaning and other maintenance activities for your cleaning equipment.

8. Failure to establish and implement procedures for acceptance of incoming product, in-process product and finished device acceptance to ensure that each product run or lot of finished device have met its acceptance criteria [21 CFR 820.80].

9. Failure to establish and implement procedures to ensure that device history records for each batch, lot or unit are maintained to demonstrate that the device was manufactured in with the Device Master Record and Quality System Regulation [21 CFR 820.184]. Specifically, your firm does not maintain any records describing the date of manufacture, quantities manufactured, quantities released, or the acceptance records.

10. Failure to establish and implement procedures to ensure that all complaints are processed in a uniform and timely manner [21 CFR 820.198].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violation identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no request for Certificates For

Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunctions, and/or civil penalties.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Thomas L. Sawyer, Director, Compliance Branch and a copy to Dannie E. Rowland, Compliance Officer at U.S. Food and Drug Administration, 19900 MacArthur Boulevard, Suite 300, Irvine, California 92612-2445.

Sincerely,

Acting District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
601 North 7th Street, MS-357
P.O. Box 942732
Sacramento, CA 94234-7320

Exhibit RLS-5

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

m3412n

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-29

February 10, 2000

Carlos M. Campos, President & CEO
Safety Disposal System, Inc.
1100 25th Street, Suite 7B
West Palm Beach, Florida 33407

Dear Mr. Campos:

We are writing to you because on January 10 through 18, 2000 FDA Investigator Bill Tackett, Jr. inspected your facility and collected information that revealed serious regulatory problems involving your firm's reprocessing of medical devices (reusable sharps containers).

Under the Federal Food, Drug, and Cosmetic Act (the Act), the products that your firm reprocesses are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers conform to the Quality System (QS) regulations for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that devices that you sort and clean for further reprocessing are adulterated within the meaning of section **501(h)** of the Act, in that the methods used in, or the facilities or controls used for their manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

QS Regulation/GMPs

1. Failure to establish a quality policy as required by 21 CFR 820.20. For example, there is no written policy establishing the objectives for and commitment to quality (FDA 483, Item #1).

2. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system pursuant to a defined schedule to ensure the quality system meets the requirements of the established quality policy and objectives as required by 21 CFR 820.20(c). For example, no reviews have been conducted to determine the effectiveness or suitability of the quality system (FDA 483, Item #2).

3. Failure to establish procedures for quality audits and conduct of audits to assure the quality system is in compliance with the established quality system requirements and the effectiveness of the quality system as required by 21 CFR 820.22. For example, no internal quality audits have been conducted (FDA 483, Item #3).

4. Failure to validate the processes for cleaning and sanitizing reusable sharps containers as required by 21 CFR 820.75. For example, no validation has been conducted (FDA 483, Item #7).

5. Failure to establish a complaint handling system as required by 21 CFR 820.198. For example, no procedures have been established or are maintained for receiving, reviewing and evaluating complaints by a formally designated unit (FDA 483, Item #4).

6. Failure to establish and maintain procedures for acceptance of incoming new product and product being returned for reuse as required by 21 CFR 820.80. For example, no acceptance activities are conducted including inspection, tests or other verification of activities involving condition, cleaning and sanitation (FDA 483, Item #6).

7. Failure to establish and maintain procedures for the calibration, adjustment or maintenance of process equipment as required by 820.70(g). For example, no inspections were conducted pursuant to your own procedures, which require a daily inspection of the Reusable Container Wash and Disinfection System (FDA 483, Item #8).

8. Failure to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications as required by 21 CFR 820.70(a). For example, there are no procedures available describing the current washing system in use (FDA 483, Item #11).

The specific QS/GMP violations noted in this letter and in the List of Observations (FDA 483) issued to Peter A. Light, Chief of Operations at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the awards of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Reva J. Melton
Acting Director
Florida District