Exhibit RLS-6

Exhibit RLS-6

· DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

m 5251 n

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

HAND-DELIVERED

WARNING LETTER

FLA-00-34

March 7, 2001

Carlos M. Campos, President
Safety Disposal System, Inc.
6175 N.E. 153rd Street, suite 324
Miami Lakes, Florida 33014

Dear Mr. Campos:

During an inspection of your establishment located in West Palm Beach, Florida on January 10-12 & 16, 2001, FDA Investigator Michelle S. Dunaway determined that your establishment is a specification developer, reprocessor and distributor of reusable sharps containers, a medical device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Under the Federal Food, Drug, and Cosmetic Act (the Act), the product(s) that your firm manufactures/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 above-stated inspection revealed that this device is 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/reprocessing, packing, storage, or installation are not in conformance with the Quality System regulations for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

QS Regulation/GMPs

1. Your firm failed to establish a policy and objectives for, and commitment to, quality that management with executive responsibility shall ensure is understood, implemented, and maintained at all levels of the organization as required by 21 CFR 820.20. For example, the plant manager responsible for the supervision of the sharps container quality system, and individuals performing sharps container reprocessing have not been trained and are unfamiliar with the Quality System requirements. Your quality policy has not been implemented. Corrections to these observations were promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item # 1) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item #s 1-3).

2. Your firm failed to conduct management reviews covering the overall suitability of your quality system as required by 21 CFR 820.20(c). For example, the only area of the reprocessing operation that has been reviewed is the container washing area on May 4, and June 28, 2000. Corrections to this observation were promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item # 2) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item # 4).

3. Your firm failed to conduct quality audits that address all quality system requirements as required by 21 CFR 820.22. For example, the only areas of the reprocessing system that have been audited were the container washing area including the number of containers washed and rejected. Corrections to these observations were promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item # 3) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item #5).

4. Your firm failed to establish and maintain procedures for implementing corrective and preventive action as required by 21 CFR 820.100. Correction to this observation was promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item #s5 & 9) and Warning Letter #FLA-00-29 issued on February 10, 2000. The same observations were again made and issued to your firm on January 18, 2000, which was listed on the Inspectional Observations (FDA 483, Item # 15).

5. Your firm failed to validate the cleaning and disinfection processes of the reprocessing operation as required by 21 CFR 820.75(a) & (c). For example, the current process was implemented only three months ago, which replaced germicidal soap with an unspecified level of chlorine/bleach and changed the temperature of the wash from 180°F to an uncontrolled temperature range. It was also determined during the inspection that the water heater coil had been broken for three months and had not been replaced. The temperature of "hot" water was observed to be 65°F. Correction to this observation was promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item # 7) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item # 6).

6. Your firm failed to establish complaint handling procedures and there is no record that a failure investigation was conducted of a confirmed complaint required by 21 CFR 820.198. For example, a rack of sharps containers were released without being cleaned and no documented investigation was made. Correction to this observation was promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item #s 4 & 11) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item #s 7 & 10).

7. Your firm failed to establish and maintain written acceptance criteria for reprocessed sharps containers to ensure that each production run, lot, or batch of reprocessed devices meets acceptance criteria as required by 21 CFR 820.80(d). For example, leakage, physical condition, lid closeability and labeling are not included in the criteria for release. There is no specified sampling plan and acceptance activities are not documented unless one or more containers are rejected. A field examination of released sharps containers revealed one container that had rust colored stains on the lid opening, one container had an approximate quarter sized hole just below the lid, and at a minimum, five containers were missing the removable sliding door. Correction to this observation was promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item #6) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item #s 9 & 12).

8. Your firm failed to establish and maintain procedures for the current cleaning and disinfection processes as required by 21 CFR 820.70(a), (b). For example, chlorine and water temperature levels are not specified, controlled or monitored. Chlorine levels on January 11 and 12, 2000 were observed to below 0.5ppm and the washer temperature to be 100°F and 70°F later and 200 ppm and 70°F, respectively. Correction to this observation was promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item #11) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item #10).

9. Your firm failed to establish and maintain procedures to prevent contamination of equipment or product substances that could reasonably be expected to have an adverse effect on product quality as required by 21 CFR 820.70(e). For example, an individual responsible for handling disinfected sharps containers was observed to be using gloves that had been used during the lid cleaning process that had a visible rust colored substance. Cloth towels are reused by laying them or tying them to a large fan. These towels are used for an unspecified or unknown number of day's production. The restrooms for workers do not have hot running water and there was nothing available for drying hands except for toilet paper (FDA 483, Item #11).

10. Your firm failed to maintain device history records (DHR's) to ensure that each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with specifications listed in the device master record (DMR) as required by 21 CFR 184. For example, employees marked the "Daily Protocol Parameter Log" for approximately three months, while the water heater coil was broken, "Yes" reporting the water temperature was 180°F even though the temperature was observed to be 100°F or below. These logs were reviewed and maintained by the Plant manager (FDA 483, Item #13.

11. Your firm failed to ensure that each DMR is prepared and approved as required by 21 CFR 820.181. For example, the DMR fails to include device and labeling specifications that address the useful life of sharps containers and the level required to effect disinfection (FDA 483, Item #16).

The specific violations noted in this letter and in the List of Observations (FDA 483) issued to Jorge Barroso, Plant Manager, 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 award of contracts. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contract, and to resume marketing clearance, and export clearance for products manufactured at your facility, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that they have conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the device QS regulation/GMPs (21 CFR Part 820). You should also submit a copy of the consultant's report, and your certification that you have reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report.

The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates:

- Date and certification of initial audit by consultant and firm (to be conducted within four (4) months of the receipt of this letter).

- Monthly reports and timeline of progress to achieve compliance to be submitted by the last day of each month until all corrective actions have been corrected not to exceed 4 months.

- Final certification of accomplished corrective and preventive actions related to this Warning Letter to be submitted no later than June 30, 2001.

- An annual certification and a report of an annual audit by an outside consultant for each of the next two years covering your firm's current status with regard to the Quality Systems regulation.

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. Any further distribution of this product is made on your own responsibility.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) 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.

You should also advise your intention to continue or cease distribution of the product in writing, until your firm's level of compliance with the Quality System regulation can be verified by the FDA .

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,

Emma Singleton
Director, Florida District

Exhibit RLS-7

Exhibit RLS-7

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

INITIAL REGISTRATION OF DEVICE ESTABLISHMENT

(Shaded Areas are for FDA Use Only)

Form Approved: OMB No. 0910-0387
Expiration Date: March 31, 2005

Print

VALIDATION

RETURN THIS FORM TO: Food and Drug Administration, Center for Devices and Radiological Health, (HFZ-308), 9200 Corporate Blvd., Rockville, MD 20850-4015

1. REGISTRATION NO.

Public reporting burden for this collection of information is estimated to average .25 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-308)
9200 Corporate Blvd.
Rockville, MD 20850-4015

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C.331(p)). Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2) and may be a violation of 18 U.S.C. 1001.

SECTION A

2. ESTABLISHMENT BUSINESS NAME		3. RECORD DATE (Mo.) (Day) (Year)		
Sure-Way Systems, Inc.		05	24	2005
4. NUMBER AND STREET	**5. CITY**	**6. STATE**	**7. ZIP/POSTAL CODE**	
107 South Parkmont	Butte	MT	59701	
8. FOREIGN STATE	**9. FOREIGN COUNTRY**	**10. PREPRODUCTION REGISTRATION**		
		☐ YES ☒ NO		

11. ESTABLISHMENT TYPE *(See Instruction Booklet)*

☐ Contract Manufacturer ☐ Manufacturer ☐ Repacker/Relabeler ☒ Specification Developer ☐ Reprocessor of Single-Use Device
☐ Contract Sterilizer ☐ Remanufacturer ☐ Initial Distributor/Importer ☐ Foreign Exporter

SECTION B

12. OWNER/OPERATOR BUSINESS NAME		13. OWNER/OPERATOR NUMBER	
Gary Chilcott			
14. NUMBER AND STREET	**15. CITY**	**16. STATE**	**17. ZIP/POSTAL CODE**
404 Main Street	Deer Lodge	MT	59722
18. FOREIGN STATE	**19. FOREIGN COUNTRY**	**20. TELEPHONE NUMBER--IF DIFFERENT FROM THAT OF OFFICIAL CORRESPONDENT** *(Country, City, Area Code)* *(Number and Extension)*	

SECTION C

21. OFFICIAL CORRESPONDENT *(Name of Individual)*		22. BUSINESS NAME		
Gary Chilcott		Sure-Way Systems, Inc.		
23. NUMBER AND STREET	**24. CITY**	**25. STATE**	**26. ZIP/POSTAL CODE**	
404 Main Street	Deer Lodge	MT	59722	
27. FOREIGN STATE	**28. FOREIGN COUNTRY**	**29. E-MAIL ADDRESS**		
		surewaymt@aol.com		
30. TELEPHONE NUMBER *(Country, City, Area Code)* *(Number and Extension)*		**31. FAX NUMBER** *(Country, City, Area Code) (Number)*		
United States, Deer Lodge, (406) 846-2033		United States, Deer Lodge, (406) 846-7842		

SECTION D

32. OTHER BUSINESS TRADING NAMES
(Enter any other name which the establishment in field #2 uses. Do not list Registered trademarks or names of private label distributors. This is usually any name such as a brand name which is not the firm name.)

SEQ	BUSINESS NAME	SEQ	BUSINESS NAME
SO1		SO3	
SO2		SO4	

SECTION E

33. SIGNATURE OF OFFICIAL CORRESPONDENT	34. TITLE
Gary Chilcott	CEO/Pres

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Exhibit RLS-8

Exhibit RLS-8

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

INITIAL REGISTRATION OF DEVICE ESTABLISHMENT

(Shaded Areas are for FDA Use Only)

Form Approved: OMB No. 0910-0387
Expiration Date: March 31, 2005

Print

VALIDATION

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Center for Devices and Radiological Health (HFZ-308)
9200 Corporate Blvd.
Rockville, MD 20850-4015

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SECTION A

2. ESTABLISHMENT BUSINESS NAME	3. RECORD DATE (Mo.)	(Day)	(Year)
Sure-Way Systems, Inc.	05	24	2005

4. NUMBER AND STREET	5. CITY	6. STATE	7. ZIP/POSTAL CODE
13200 58th North #2	Clearwater	FL	33760

8. FOREIGN STATE	9. FOREIGN COUNTRY	10. PREPRODUCTION REGISTRATION
		☐ YES ☒ NO

11. ESTABLISHMENT TYPE *(See Instruction Booklet)*

☐ Contract Manufacturer ☐ Manufacturer ☐ Repacker/Relabeler ☒ Specification Developer ☐ Reprocessor of Single-Use Device
☐ Contract Sterilizer ☐ Remanufacturer ☐ Initial Distributor/Importer ☐ Foreign Exporter

SECTION B

12. OWNER/OPERATOR BUSINESS NAME	13. OWNER/OPERATOR NUMBER
Gary Chilcott	

14. NUMBER AND STREET	15. CITY	16. STATE	17. ZIP/POSTAL CODE
04 Main Street	Deer Lodge	MT	59722

18. FOREIGN STATE	19. FOREIGN COUNTRY	20. TELEPHONE NUMBER–IF DIFFERENT FROM THAT OF OFFICIAL CORRESPONDENT *(Country, City, Area Code)* *(Number and Extension)*

SECTION C

21. OFFICIAL CORRESPONDENT *(Name of Individual)*	22. BUSINESS NAME
Gary Chilcott	Sure-Way Systems, Inc.

23. NUMBER AND STREET	24. CITY	25. STATE	26. ZIP/POSTAL CODE
404 Main Street	Deer Lodge	MT	59722

27. FOREIGN STATE	28. FOREIGN COUNTRY	29. E-MAIL ADDRESS
		surewaymt@aol.com

30. TELEPHONE NUMBER *(Country, City, Area Code)* *(Number and Extension)*	31. FAX NUMBER *(Country, City, Area Code) (Number)*
United States, Deer Lodge, (406) 846-2033	United States, Deer Lodge, (406) 846-7842

SECTION D

32. OTHER BUSINESS TRADING NAMES
(Enter any other name which the establishment in field #2 uses. Do not list Registered trademarks or names of private label distributors. This is usually any name such as a brand name which is not the firm name.)

SEQ	BUSINESS NAME	SEQ	BUSINESS NAME
SO1		SO3	
SO2		SO4	

SECTION E

33. SIGNATURE OF OFFICIAL CORRESPONDENT	34. TITLE
Gary Chilcott	CEO/Pres.

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Exhibit RLS-9

Exhibit RLS-9

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

INITIAL REGISTRATION OF DEVICE ESTABLISHMENT

(Shaded Areas are for FDA Use Only)

Form Approved: OMB No. 0910-0387
Expiration Date: March 31, 2005

Print

VALIDATION

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Center for Devices and Radiological Health (HFZ-308)
9200 Corporate Blvd.
Rockville, MD 20850-4015

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SECTION A

2. ESTABLISHMENT BUSINESS NAME		3. RECORD DATE (Mo.)	(Day)	(Year)
Sure-Way Systems, Inc.		05	24	2005
4. NUMBER AND STREET	5. CITY	6. STATE	7. ZIP/POSTAL CODE	
1019 4th Ave SW	Valley City	ND	58072	
8. FOREIGN STATE	9. FOREIGN COUNTRY	10. PREPRODUCTION REGISTRATION ☐ YES ☒ NO		

11. ESTABLISHMENT TYPE *(See Instruction Booklet)*

☐ Contract Manufacturer ☐ Manufacturer ☐ Repacker/Relabeler ☒ Specification Developer ☐ Reprocessor of Single-Use Device
☐ Contract Sterilizer ☐ Remanufacturer ☐ Initial Distributor/Importer ☐ Foreign Exporter

SECTION B

12. OWNER/OPERATOR BUSINESS NAME		13. OWNER/OPERATOR NUMBER	
Gary Chilcott			
14. NUMBER AND STREET	15. CITY	16. STATE	17. ZIP/POSTAL CODE
404 Main Street	Deer Lodge	MT	59722
18. FOREIGN STATE	19. FOREIGN COUNTRY	20. TELEPHONE NUMBER–IF DIFFERENT FROM THAT OF OFFICIAL CORRESPONDENT *(Country, City, Area Code)* *(Number and Extension)*	

SECTION C

21. OFFICIAL CORRESPONDENT *(Name of Individual)*		22. BUSINESS NAME	
Gary Chilcott		Sure-Way Systems, Inc.	
23. NUMBER AND STREET	24. CITY	25. STATE	26. ZIP/POSTAL CODE
404 Main Street	Deer Lodge	MT	59722
27. FOREIGN STATE	28. FOREIGN COUNTRY	29. E-MAIL ADDRESS	
		surewaymt@aol.com	

30. TELEPHONE NUMBER *(Country, City, Area Code)* *(Number and Extension)*	31. FAX NUMBER *(Country, City, Area Code) (Number)*
United States, Deer Lodge, (406) 846-2033	United States, Deer Lodge, (406) 846-7842

SECTION D

32. OTHER BUSINESS TRADING NAMES
(Enter any other name which the establishment in field #2 uses. Do not list Registered trademarks or names of private label distributors. This is usually any name such as a brand name which is not the firm name.)

SEQ	BUSINESS NAME	SEQ	BUSINESS NAME
SO1		SO3	
SO2		SO4	

SECTION E

33. SIGNATURE OF OFFICIAL CORRESPONDENT	34. TITLE
Gary Chilcott	CEO / Pres.

FORM FDA 2891 (7/02) PREVIOUS EDITIONS ARE OBSOLETE.

Created by: FSC Media Arts (301) 443-2454 EF

Exhibit RLS-10

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

INITIAL REGISTRATION OF DEVICE ESTABLISHMENT

(Shaded Areas are for FDA Use Only)

Form Approved: OMB No. 0910-0387
Expiration Date: March 31, 2005

Print

VALIDATION

RETURN THIS FORM TO: Food and Drug Administration, Center for Devices and Radiological Health, (HFZ-308), 9200 Corporate Blvd., Rockville, MD 20850-4015

1. REGISTRATION NO.

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Center for Devices and Radiological Health (HFZ-308)
9200 Corporate Blvd.
Rockville, MD 20850-4015

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SECTION A

2. ESTABLISHMENT BUSINESS NAME		3. RECORD DATE (Mo.)	(Day)	(Year)
Sure-Way Systems, Inc.		05	24	2005
4. NUMBER AND STREET	**5. CITY**	**6. STATE**	**7. ZIP/POSTAL CODE**	
807 Market Street	Decatur	AL	35601	
8. FOREIGN STATE	**9. FOREIGN COUNTRY**	**10. PREPRODUCTION REGISTRATION**		
		☐ YES ☒ NO		

11. ESTABLISHMENT TYPE *(See Instruction Booklet)*

☐ Contract Manufacturer ☐ Manufacturer ☐ Repacker/Relabeler ☒ Specification Developer ☐ Reprocessor of Single-Use Device
☐ Contract Sterilizer ☐ Remanufacturer ☐ Initial Distributor/Importer ☐ Foreign Exporter

SECTION B

12. OWNER/OPERATOR BUSINESS NAME		13. OWNER/OPERATOR NUMBER	
Gary Chilcott			
14. NUMBER AND STREET	**15. CITY**	**16. STATE**	**17. ZIP/POSTAL CODE**
404 Main Street	Deer Lodge	MT	59722
18. FOREIGN STATE	**19. FOREIGN COUNTRY**	**20. TELEPHONE NUMBER–IF DIFFERENT FROM THAT OF OFFICIAL CORRESPONDENT** *(Country, City, Area Code)* *(Number and Extension)*	

SECTION C

21. OFFICIAL CORRESPONDENT *(Name of Individual)*		22. BUSINESS NAME		
Gary Chilcott		Sure-Way Systems, Inc.		
23. NUMBER AND STREET	**24. CITY**	**25. STATE**	**26. ZIP/POSTAL CODE**	
404 Main Street	Deer Lodge	MT	59722	
27. FOREIGN STATE	**28. FOREIGN COUNTRY**	**29. E-MAIL ADDRESS**		
		surewaymt@aol.com		

30. TELEPHONE NUMBER *(Country, City, Area Code)* *(Number and Extension)*	31. FAX NUMBER *(Country, City, Area Code) (Number)*
United States, Deer Lodge, (406) 846-2033	United States, Deer Lodge, (406) 846-7842

SECTION D

32. OTHER BUSINESS TRADING NAMES
(Enter any other name which the establishment in field #2 uses. Do not list Registered trademarks or names of private label distributors. This is usually any name such as a brand name which is not the firm name.)

SEQ	BUSINESS NAME	SEQ	BUSINESS NAME
SO1		SO3	
SO2		SO4	

SECTION E

33. SIGNATURE OF OFFICIAL CORRESPONDENT	34. TITLE
Gary Chilcott	CEO/Pres

FORM FDA 2891 (7/02) PREVIOUS EDITIONS ARE OBSOLETE.

Exhibit RLS-11

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DEVICE LISTING

Form Approved: OMB No. 0910-0387.
Expiration Date: March 31, 2005.

Complete and Return to: **Food and Drug Administration**
Center for Devices and Radiological Health
Information Processing and Office Automation Branch (HFZ-308)
9200 Corporate Blvd.
Rockville, MD 20850-4015

Print

NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act, (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(g)(2) and may be a violation of 18 U.S.C. 1001.

1. DOCUMENT NUMBER	2. REASON FOR SUBMISSION	3. REPORT DATE			4. OWNER / OPERATOR NUMBER
E232894	☒ New Listing	MO.	DAY	YR.	
1a. PREVIOUS DOCUMENT NUMBER	☐ Update to Device Already Listed	5	24	5	
	☐ Discontinuing Product Line				

5. OWNER / OPERATOR NAME *(changes in owner/operator must be reported using form FDA 2891a or by letter)*
Sure-Way Systems, Inc.

6. ADDRESS
a. NUMBER and STREET 404 Main Street

b. CITY, STATE, ZIP CODE or CITY, FOREIGN STATE, POSTAL CODE
Deer Lodge, MT 59722

c. FOREIGN COUNTRY

7. CLASSIFICATION NAME *(refer to www.fda.gov/cdrh/prodcode.html)*
Sharps Container — Internet Link

8. CLASSIFICATION NUMBER
FMI — Internet Link

9. PROPRIETARY NAME *(Brand Name(s))*
Sure-Way Systems Reusable Sharps Container

10. COMMON OR USUAL NAME(S)
Sharps Container

11. ESTABLISHMENT NAME AND ADDRESS
(Identification of Sites Where Listed Device is Produced)
(Name, Street Number, City, State or Country, ZIP or Postal Code)

REGISTRATION NO.	ESTABLISHMENT TYPE									
	F	M	B	R	S	X				
A NONE Sure-Way Systems, Inc. 107 South Parkmont, Butte, MT 59701					X					
B NONE Sure-Way Systems, Inc. 1019 4th Ave SW, Valley City, ND 58072					X					
C NONE Sure-Way Systems, Inc. 807 Market Street, Decatur, AL 35601					X					
D NONE Sure-Way Systmes, Inc. 13200 58th North #2, Clearwater, FL 33760					X					

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:
Food and Drug Administration
Center for Devices and Radiological Health
Information Processing and Office Automation Branch (HFZ-308)
9200 Corporate Blvd.
Rockville, MD 20850-4015

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

12. SIGNATURE
Gary Chilcott

13. TYPED OR PRINTED NAME, AND TITLE
Gary Chilcott, President/CEO

FORM FDA 2892 (4/02) PREVIOUS EDITIONS ARE OBSOLETE.

Created by: PSC Media Arts (301) 443-2454 EF

Exhibit RLS-12

K992626

Sure-Way Sharps Disposal Services

Division of Sure-Way Systems, Inc.

Exhibit RLS-12

AUG 5 1 25PM '99

Office of Device Evaluation - 510 (k)
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

ATTN: Infection Control Devices Branch

RE: 501 (k) Premarket Notification for Reusable Sharps Container

Dear Sir or Madam:

Pursuant to section 510(K) of the Federal Food, Drug and Cosmetic Act (FDC Act) and the requirements of 21 C.F.R. § 807.87, Sure-Way Systems, Inc. is submitting this premarket notification to market its Reusable Sharps Container, which are waste receptacles intended to hold discarded needles.

The information contained in Attachments 3, 4, 5 and 6 herein constitutes proprietary, trade secret and/or confidential business information, and has therefore been marked "Confidential." Sure-Way Systems, Inc. hereby requests that this information be afforded confidential treatment within the meaning of the Freedom of Information Act, 5 U.S.C. § 20.61, and that such information not be divulged to unauthorized persons. We also ask that you consult with Sure-Way Systems, Inc. as provided in 21 C.F.R. § 20.45, before making any part of this submission publicly available.

We trust that the information provided in this notification will be sufficient to enable FDA to find the Reusable Sharps Container substantially equivalent to its predicate device.

Please direct any questions or requests for additional information to the undersigned.

Sincerely,

Sure-Way Systems, Inc.

By: Gary Chilcott

Gary Chilcott
CEO/President

310 Harry Bridges Blvd. Wilmington, CA 90744 310-522-0150 FAX 310-522-0431

5K 25

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510(k) PREMARKET NOTIFICATION CHECKLIST

ITEM	COMMENT
1. Device trade or proprietary name section I	See 510(k) notice
2. Device common or unusual name or classification name	See 510(k) notice section I
3. Manufacturer/distributor information	See 510(k) notice section II
4. Class into which the device is classified	See 510(k) notice section III
5. Classification Panel	See 510(k) notice section III
6. Action taken to comply with section 514 of the Act	Not applicable- no performance standards or special controls apply.
7. Proposed labels, labeling and advertisements (if applicable) that describe the device, its intended use, and directions for use	See Attachment 1
8. A 510(k) Summary or a 510(k) Statement	See Attachment 7
9. For class III devices only, a class III certification and a class III summary	Not applicable, this is a class I device
10. Photographs of the device	See Attachment 3 (engineering drawings)
11. Engineering drawings for the device with dimensions and tolerances	See Attachment 3
12. The marketed device(s) to which equivalence is claimed including labeling and description of the device	See 510(k) notice section VI and Attachment V
13. Statement of similarities and/or differences with marketed device(s)	See 510(k) section IX
14. Data to show consequences and effects of a modified device	Not applicable
15. Submitter's name and address	See 510(k) notice section XIII
16. Contact person, telephone/fax number	See 510(k) notice section XIV
17. Representative/Consultant, if applicable	Not applicable
18. Table of Contents with pagination	See 510(k) notice page i
19. Comparison table of the new device to the marketed device(s)	See Attachment 6

20. Action taken to comply with voluntary standards	No voluntary standards apply
21. Performance data	
a. marketed device	
1. bench testing	Not applicable
2. animal testing	Not applicable
3. clinical data	Not applicable
b. new device	
1. bench testing	See Attachment 5
2. animal testing	Not applicable
3. clinical testing	Not applicable
22. Sterilization information	Not applicable
23. Software information	Not applicable
24. Hardware information	Not applicable
25. Is this device subject to issues that have been addressed in specific guidance documents(s)?	Yes
26. Truthful and Accurate Statement	See Attachment 8
27. Indications for Use Sheet	See Attachment 9

SURE-WAY SYSTEMS, INC.

510(K) PREMARKET NOTIFICATION

FOR

REUSABLE SHARPS CONTAINERS

Sure-Way Systems, Inc.
310 Harry Bridges Boulevard
Wilmington, CA 90744
(310)522-0150

Table of Contents

Table of Contents
Continued

Attachments

The following information is provided as required by 21 C.F.R. § 807.87 and FDA's "Draft 510(k) Guidance on Sharps Containers" (October 1993):

I. Name of Device

A. Classification Name: Accessory to hypodermic needle
B. Common Name: Sharps Container
C. Proprietary Name: Sure-Way Reusable Sharps Container

II. Manufacturer/Distributor

The manufacturer of the Reusable Container is:

L & H Molds and Engineering
2240 East Cedar Street
Ontario, CA 91761
(909) 930-1550

The establishment registration number of the manufacturer is pending

The distributor and entity submitting this 510(k) notification is:

Sure-Way Systems, Inc.
310 Harry Bridges Boulevard
Wilmington, CA 90744
(310) 522-0150

The establishment registration number of the distributor is pending

III. Product Code/Classification: 80 FMI; Class II

IV. Performance Standards

No FDA - established performance standards or special controls apply.

V. Labeling/Advertising

The proposed labels which will appear on the devices are enclosed as Attachment 1. Promotional Literature is enclosed as Attachment 2.

The sharps containers are delivered by Sure-Way Systems, Inc. to the facility for installation. Placement of the container at the facility is done by facility staff at their desired location. Trained Sure-Way representatives check all container sites on a regular schedule and exchange all containers once they have reached the fill point. Another option is for the health care facility employees to exchange the containers and bring them to a secured central location for collection by Sure-Way staff. The exchanged containers are brought back to the Sure-Way facility for processing, i.e., automated container dumping, cleaning and waste disposal.

VI. General Description

A. The Sure-Way Reusable Container is a reusable plastic container into which used needles and other medical waste sharps are discarded. It is a nonsterile device for nonsterile applications. Engineering drawings for the container are provided in Attachment 3.

B. The volume of this device is 14.5 liters.

C. The containers are injection molded from high density polyethylene plastic resin at an average wall thickness of 1/8" (0.125"). Attachment 4 sets forth the specifications for this material, which is semi-opaque.

D. The intended locations for use are any areas in a medical, dental, veterinarian, or other health care facility where there is a need for used sharps disposal.

E. The projected life expectancy of the device is at least five (5) years. Polyethylene is a non-degrading material. Other sharps containers using the same material for the same purpose have remained in use over five (5) years without showing failure.

F. Upon their return to the Sure-Way facility, the containers are removed from a security cart one at a time. The container locking pin is removed by the operator. The container is then placed into a mechanical dumper-washer. A mechanical gripper removes the top from the container base. The gripper lifts off the cover and carries it onto a conveyer and on through the washing equipment. The container base is then inverted, the sharps and other material are then dumped into a cart and mechanically dumped into an autoclave bin or incinerator for decontamination and disposal. The entire process will use one or two employees. The sharps container base, like the top, is washed and sanitized with chemicals and 180 degree water and steam.

VII. Design Features of Container

A. Each container is lockable. Each container has a bayonet style lid closure that horizontally slides into place and is removed mechanically for emptying and cleaning. The lid features nylon locking push pin fastener to further help hold the lid in place.

The container lid features a horizontal drop entry hole that is approximately 9" X 2.25". The container has a paddle wheel security system which prevents unauthorized access to the contents, thus minimizing exposure. The container lid also features an attached top that closes the entire entry port and locks into place with a security locking pin.

B. The device is puncture resistant.

C. The device is leakproof on the sides and bottom.

D. The device is labeled in accordance with OSHA requirements and ANSI standards. A biohazard label (Attachment 1) is permanently affixed to the front and back of the container by adhesive backing.

E. The container features four raised legs for stability when used in a free standing mode. The device is capable of maintaining a stable, upright position during use in a free standing mode. The container system also features a locking mounting bracket for additional stability and security.

F. The device does not incorporate any features to break, bend, or shear needles.

G. The device does not feature a needle unwinder.

VIII. Test Methods for Design Features

A. The impact resistance of the Reusable Sharps Container was determined in accordance with the U.S. Department of Transportation "Drop Test" (49 C.F.R. § 178.603). The laboratory test report is enclosed as Attachment 5. The following is a summary of the test and results.

Method: The Reusable Sharps Containers were filled with medical waste to a density of 3.76 pounds per cubic foot. After stabilizing for 4 hours, the test units were dropped on a concrete floor from a height of 39".

Results: The Reusable Containers met with the requirements set forth in 49 C.F.R. § 178.603 when using nylon locking push pin fasteners for the lids. The units did not exhibit any signs of damage from the test.

B. The puncture resistance of the Reusable Containers were determined in accordance with proposed ASTM Task Force F04.65.01, draft #12, dated 6/11/92. The test report is enclosed as Attachment 5. The following is a summary of the test and the results.

Method: A sample of the thinnest area on the container was cut for testing. The container was subjected to 3 penetrations by a hypodermic needle attached to a force gauge, which was mounted to a press.

NB

Results: All samples met the requirements of ASTM F04.65.01. Draft #12, which an average puncture resistance greater than 3.4 pounds.

C. There are no standard or test methods for the overfill detection design feature. A "fill line" is clearly marked on each label to identify the capacity of the container. A legend "DO NOT FILL ABOVE THIS LINE" is prominently displayed along the line. In addition, as explained above, the containers are serviced on a regularly scheduled basis, thus reducing the possibility of an overfilled container.

D. Leak Resistance was determined in accordance with the ECRI test method (health Devices, Aug.- Sept. 1993, ECRI Vol. 22, Nos. 8-9, P. 384). The laboratory test is enclosed as Attachment 5. The following is a summary of the tests and results:

Method: The containers were placed on a level surface and filled with water to the top of the container. After 24 hours the containers were checked for loss of liquid.

Results: All containers retained the water for the 24 hour time period, therefore passing the test.

E. Sharps Access and Closure. There are no standards or test methods for this design feature. The container has a horizontal access port in the lid for depositing sharps. The entry port is approximately 9" X 2.25".

F. Stability was determined in accordance with the ECRI test Method(id.)

Method: The container mounting bracket was fastened to a plywood board. With the sharps container attached to the bracket, the board was rotated and/or tilted but the containers did not topple because of the bracket construction. The containers were positioned on a flat floor without the bracket.

Results: All containers remained stable without tipping in accordance with OSHA specifications 29 C.F.R.1910.1030.

G. Mounting Accessories/Locking Mechanism. The mounting bracket for the reusable container has a locking mechanism that prevents unauthorized removal of the container. The mounting accessories allow for easy container replacement.

H. Handling (safe transportation features). See tests described in paragraphs A, B, C and D above.

I. Capacity was determined using the ECRI test method (id., at p. 387) (see attachment 5), as follows.

Method: The container was filled with water to capacity, and the volume of water was measured.

Results: The total capacity of the container was within 10% of the specified volume, thus passing the test.

IX. Comparison to a Predicate Device

The Sure-Way Reusable Sharps Container is substantially equivalent to MedX and BioMed Sharps Containers. The medX predicated device was cleared for marketing by the FDA under 510(k). Notification #K943771. A side by side comparison of the design features and specifications of the MedX reusable sharps container and the Sure-Way Reusable Sharps Container is enclosed as Attachment 6.

There are no significant functional differences between the predicate device and this new device. The basic differences relate to the construction and added features.

- The MedX reusable container was blow molded, resulting in the average wall thickness of 0.070". The Sure-Way Reusable Sharps Container was injection molded, resulting in an average wall thickness of 0.125".

- The lid and container base assembly of the Sure-Way Reusable Container is designed to be compatible with the mechanical dumping and washing equipment.

- The Sure-Way Reusable Container offers a tortuous path entry to minimize exposure of the contents to humans.

Since the Sure-Way Reusable Container has the same intended use, principles of operation and technological characteristics, as it's predicate device, the MedX reusable sharps container, no new issues of safety or effectiveness are raised.

X. Sterilization Information

Not applicable.

XI. Statements

Attachment 7 of this submission contains the company's 510(k) statement. Attachment 8 contains the company's Truthful and Accurate Statement.

XII. Indications for Use Sheet

Attachment 9 contains the completed "Indications for Use Sheet.

XIII. Confidentiality

Some of the material in this submission may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. These item have been marked "CONFIDENTIAL." We ask that you consult with the Company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

1446

XIV. Submitter's Name and address

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

Telephone: 310-522-0150
Fax: 310-522-0431

XV. Contact Person and Telephone/Fax Numbers

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

Telephone: 310-522-0150
Fax: 310-522-0431

Exhibit RLS-13

DRAFT

GUIDANCE ON THE CONTENT AND FORMAT OF PREMARKET NOTIFICATION [510(k)] SUBMISSIONS FOR SHARPS CONTAINERS

October 1993

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of General and Restorative Devices
Infection Control Devices Branch

DRAFT

A. Scope

This document pertains to sharps containers and secondary sharps containers. A secondary container holds the sharps container, if leakage is possible (refer to OSHA regulation 29 CFR 1910.1030(d)(4)(iii)(A)(3)).

B. Introductory Information

1. The labeling or promotional material for the sharps container may not state that the device is FDA approved or cleared. The applicant may be able to claim the device meets OSHA regulations on Bloodborne Pathogens, 29 CFR 1910.1030, if such a statement is permitted under OSHA regulations and statutes.

2. FDA 510(k) clearance does not preclude OSHA from finding the device and/or its use to be violative under OSHA regulations. If the design is found deficient by OSHA, subsequent to a finding of substantial equivalence by FDA, and it is modified to render it acceptable to OSHA, then a new 510(k) should be submitted noting the modifications.

3. FDA and OSHA are working together to implement adequate infection control practices to reduce the risk of bloodborne infections. FDA is not enforcing the OSHA regulations, per se. Rather, FDA evaluates whether a sharps container has features that are consistent with current good infection control practices, for instance, as expressed in the OSHA Bloodborne Pathogen regulations related to engineering and work practice controls. OSHA engineering controls are controls that isolate or remove the bloodborne pathogens from the workplace. OSHA work practice controls are intended to help ensure that sharps containers are used in a manner that will reduce the likelihood of an exposure to infectious material by altering the manner in which sharps disposal is performed (e.g., recapping contaminated sharps only when no alternative is feasible or when such action is required by a specific medical procedure, placement of containers, and routine replacement).

4. This document is fashioned in a checklist format for use by FDA reviewers, and it is also a guide for applicants. In the blank spaces next to the requested information the FDA reviewer should indicate "Y" when the information is acceptable, "N" when not acceptable, and "NA" when not applicable. Applicants may wish to reproduce portions of the guidance and include it in the 510(k) application, with supporting information, to facilitate the review process.

5. The applicant should respond to each of the items in the guidance. Provide the information requested, state why the information is not applicable, or provide alternative information that is commensurate with the data requested.

6. Be advised that FDA has determined that devices which remove sharps off the needle hub, typically by means of an electrical charge or heat, present a new type of safety and effectiveness issue (potential for toxic emissions), and are therefore not substantially equivalent devices. The devices are Class III products requiring premarket approval, or reclassification to Class I or II before they may be marketed.

C. Standards

There are no FDA regulatory standards for sharps containers. The applicant may choose to indicate that the device meets a standard. The following are examples of standards and reference information that are relevant to sharps containers:

1. Occupational Safety and Health Administration - Occupational Exposure to Bloodborne Pathogens; final rule (29 CFR 1910.1030; Federal Register 1991 December 6; 56, No. 235:64175-82.

2. British Standard Institution - Specification for Sharps Containers (BS 7320:1990)

3. Australia Standard - Non-Reusable Containers for the Collection of Sharps Medical Items Used in Health Care Areas (AS 4031 - 1992, 1992)

4. American Society for Testing and Materials (ASTM) - Standard for puncture resistance being considered (ASTM Task Force F04.65.01)

5. Canadian Standard being considered (CAN/CSA Z316.6)

6. Health Devices, August-September 1993, ECRI, Vol. 22 Nos. 8-9.

D. Cover Letter

State at the top of the cover letter "510(k) Notification"

__ 1. Trade/Proprietary Name (Model Name and

Number):_____

__ 2. Common/Usual Name: Sharps container and/or secondary

container should be noted, as applicable.

3. Classification name (select one):

____ accessory to hypodermic needle

____ accessory to blood collection device (if dedicated to that use)

____ other: describe

4. Reason for Submission

____ new device

____ modified device

____ other: describe

__ 5. Classification: Class II for accessories noted in item

3 above.

__ 6. Panel/Procode: 80 FMI for a needle accessory

__ 7. Registration #: _____

E. Labeling

Provide copies of labels, labeling, and promotional material, All claims will be closely

scrutinized for supportive information (e.g., disease prevention claims, comparative performance claims).

_____ Biohazard labels with visible location on device

_____ General Labeling Information required under 21 CFR 801 (e.g., manufacturers name and address)

_____ Disposal Procedures

_____ Assembly/Mounting Instructions

_____ Operating Instructions

F. General Description

Provide a detailed description of the sharps container.

__ Pictures or detailed drawings (labeling may suffice)

__ Volume

__ Dimensions

__ Empty Weight

Describe the materials and form of construction

_____ Description of Materials (type of plastic, metal, cardboard, etc)

_____ Thickness of Materials (provide variations in thickness that may exist in different parts of device, and tolerances)

_____ How Device is Formed (molded, glued edges, etc.)

_____ Reusable (labeling and design must address safe disposal of sharps per OSHA regulations, i.e., no manual processing)

_____ Clarity of Material (clear, opaque, etc.)

__ Intended Location for Use (OR, patient room, etc.)

__ Describe any unique features in detail.

G. Design Features of Containers for Contaminated Sharps

Indicate if the device meets the following design features, when applicable. The basis for the list is the OSHA regulations.

__ 1. Closable

__ 2. Puncture resistant

__ 3. Leakproof on the sides and bottom

4. Labeled or color-coded:

_____ a. BIOHAZARD warning label

fluorescent orange or orange-red or predominantly so, with lettering or symbols in a contrasting color

_____ b. affixed as close as possible to the container by string, wire, adhesive, or other method that prevents loss or unintentional removal

_____ c. red container may substitute for labels

__ 5. Capable of maintaining stable, upright position

__ 6. No feature to bend, break, or shear needle (includes

blunting and melting of needle).

__ 7. OSHA Compliance Directive On Needle Unwinders

Feature to recap the needle, or remove the needle off the hub of the syringe (i.e., an unwinder as characterized by OSHA) provides for a one-handed technique (i.e. does not require holding container with the free hand).

Container with unwinder is designed so that it is stabile (secured to a wall, table, or tray) to prevent slipping during use.

The unwinder is designed to provide for a secure capture.

__ 8. Container for reusable sharps shall not be designed to

require employee to reach by hand into the container to retrieve the contaminated reusable sharps

__ 9. Container is designed to easily and safely determine if

the container is full.

10. Optional features/accessories:

_____ locked enclosure

_____ holder to secure to wall, table, etc.

H. Design Features of Secondary Containers

Indicate if the device meets the following design features, when applicable. The basis for the list is the OSHA regulations.

__ 1. Closable

__ 2. Constructed to contain all contents and prevent leakage

during handling, storage, transport, or shipping.

__ 3. Labeled or color-coded as above in G.4.

I. Specifications of Design Features

State the specifications for each of the following features. The specification should be objective and quantitative, when appropriate (e.g., puncture resistance). Refer to any standard the specification meets.

__ Impact Resistance

__ Puncture Resistance (base, sides, closure, top)

__ Overfill Detection

__ Leak Resistance (sides and bottom)

__ Sharps Access and Closure

__ Stability (maintaining upright position)

__ Mounting Accessories and any Locking Mechanism

__ Handling (safe transportation features)

__ Capacity

__ Feature to Minimize Aerosolization

__ OTHER (as applicable, e.g., electrical):

J. Design Validation Test Methods

Summarize the test methods for each of the specifications noted in item I above. The protocol must indicate pass-fail criteria and the safety and effectiveness basis for the criteria (e.g., a standard). There are tests methods indicated in the referenced standards.

K. Comparison to a Legally Marketed Sharps Container

Persons submitting 510(k)s must compare their device to a legally marketed device. FDA has recently decided to actively regulate sharps containers. FDA formal announcement of this initiative is imminent and it may provide a grace period for submission of 510(k)s.

There will be a period of time during this transition in regulatory control where some currently marketed containers are still pending FDA clearance, making confirmation of legality of a predicate device problematic in the short term Still, the applicant should provide a comparison of their device to ones available on the market and to available standards noted in item C above.

Provide a side by side comparison of design features and specifications of containers that most closely match the device being submitted for clearance.

L. Safe Medical Devices Act 510(k) Statement of Safety and

Effectiveness or 510(k) Summary of Safety and Effectiveness

__ Provide either the statement or summary as required under 21 CFR 807.92 or 807.93 (see attached).

M. Address

Submit duplicate copies (two copies) to the following address:

FDA
Document Mail Center
HFZ-401
1390 Piccard Dr.
Rockville, MD 20850

N. Contact for Questions

If there are any questions, please call:

Branch Chief
Infection Control Devices Branch
(301) 594-1307

O. Attachment

21 CFR 807.87 - 807.94.

Exhibit RLS-14

QSR Manual

820.1 Scope of this Quality System Manual

Sure-Way Sharps (SWS) conducts a reusable sharps container reprocessing business which involves the emptying and reprocessing of filled sharps containers at [redacted] waste processing facility. While the disposal of regulated medical waste from these containers is regulated by the [redacted] in accordance with a [redacted] permit, the activity of returning sharps containers to service is regulated by the U.S. Food and Drug Administration (the FDA). The FDA classifies reusable sharps containers as Class II Medical Devices, which must be prepared for repeated service in accordance with Title 21 of the Code of Federal Regulations (21 CFR).

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 accordance with current "good manufacturing practices" (GPM) 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. Apendex I contains a complete copy of 21 CFR 820.

This manual has been developed to put in place a Quality System which meets every requirement of 21 CFR 820. For this reason, the section numbering in this manual correlates directly to the applicable subsections of 21 CFR 820. For example, this section correlates to 21 CFR 820.1.

EMPLOYEE INTRODUCTION:

The 'SURE-WAY SYSTEMS' Facility Operations Manual is based on the QSR program that provides strict regulatory and operational guidelines that must be followed. This manual is intended for Sure-Way Systems employees who have been assigned duties in processing, customer service and/or managing the Reusable Sharps Container System.

Your input is critical to the effectiveness of the program. Your suggestions are not only requested but demanded, your input can and will be a part of this program. This program is laid out to facilitate your input as well as others.

This ***manual is organized by subject matter*** and references section numbers of the regulating, 21 CFR 820, and specifically outlined in the Sure-Way Systems QSR manual. The ***QSR is organized by section*** number and may be used as an easy reference for this manual. You must become familiar with these regulatory guidelines to effectively perform your duties.

Appendix, Forms, Attachments are all supportive information to facilitate you in better understanding the program and EASY ACCESS to reports and forms required for your job. It also clearly outlines what the reporting process is and who you are to submit the report to.

SECTION 1
OVERVIEW OF QSR AND APPLICATION FOR SWS

Sure-Way Sharps (SWS) is in the business of installing and servicing a proprietary reusable sharps program in healthcare facilities. There are a number of regulatory compliance issues with respect to this business from a variety of local, state and federal agencies depending on location. The primary agency which regulates our business is the Food and Drug Administration (FDA). Under the FDA guidelines, SWS is classified as a "remanufacturer". SWS has its containers manufactured under the strict FDA guidelines (ref #). In addition the process SWS uses for the processing of sharps containers and the subsequent redistribution of those containers to healthcare institutions is subject to the 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). This regulation covers the quality management and organization, device design, buildings, equipment, purchase and handling, production and process controls, packaging, labeling, device evaluation, distribution, installation, complaint handling, servicing and records of our business.

The regulations are quite clear in stating that SWS must follow an approved Quality Systems Manual (QSR), specifically designed for the reusable (remanufacturing) sharps container program. The program must be flexible. The primary objective of SWS and the QSR is to assure our products that we distribute to our healthcare clients meet the guidelines of their intended purpose.

Exhibit RLS-15

SURE-WAY SYSTEMS, INC.
Sharps Disposal Service Program
Ensuring safe disposal in the medical community

SHARPS DISPOSAL SERVICE CONTRACT

OFFICE USE ONLY

PICK-UP SCHEDULE_____
AREA_____
DATE_____
EST. WASTE OUTPUT_____

Sure-Way Systems, Inc. (hereafter referred to as **SWS)** proposes to provide the following services to _____ (hereafter referred to as **Generator)** and understands that there is a mutual agreement to the following terms and conditions:

1. **SHARPS CONTAINER REPLACEMENT AND REGULATED MEDICAL WASTE REMOVAL**

1.1 **SWS** will supply **Generator** with reusable sharps containers to service the existing ____ sharps container locations in the hospital with 510K FDA and DOT approved reusable sharps containers. This quote is for the Sure-Way Systems Smart-Sharps Service in which the **Generator** will handle all container exchanges.

1.2 The annual cost for this service is (Yr. 1)$_____ for ____ sharps container locations and _____ sharps containers annually.

1.3 There is no additional monthly charge for the 1 transport cart stationed at the facility. Any additional carts above the 1 issued are charged at $50 per cart per month.

2. **TERM**

2.1 The terms of this Agreement will commence on the date set forth in Section 11 and shall continue in effect for the period set forth in Section 2. This agreement will be automatically renewed for an additional one year term unless cancelled on or before the thirty (30) day anniversary date or each subsequent annual anniversary date.

3. TRAINING AND INSERVICES

3.1 **SWS** will provide in-service training for waste reduction and/or blood borne pathogen procedures as related to Sharps containers upon request 6 times on an annual basis. Additional seminars may be requested and performed at a set price of $100.00 per inservice.

4. FEES AND BILLING

4.1 For the services provided to **Generator** under this Agreement, **Generator** shall pay to **SWS** fees as set forth above. In the event any governmental regulation, tax, tariff, fee or surcharge is to be assessed or imposed on the transportation, storage, treatment, or disposal of the Infectious Waste Material, the fees charged by **SWS** will be increased by the amount of such tax, tariff, fee, implementation of regulations, or surcharge. Any such increase in fees shall be set forth as a separate item on the invoices submitted to **Generator.** Should additional locations be requested by the facility they will be billed at the same rate per month as the rest of the locations in the facility.

4.2 Fees set forth are firm for the term of this Agreement, with the exception of new governmental regulations that will require changes in the program that are unforeseen at this time. The increase will be only the amount needed to cover the documented increase.

4.3 Invoices will be submitted monthly by **SWS** to **Generator** and shall be paid no later than thirty (30) days from the date of invoice. Payments not paid within thirty (30) days will accrue interest at 1.5% monthly.

4.4 **SWS** shall retain records of all invoices, record of disposal, and delivery receipts for at least five (5) years.

5. TRANSFER OF WASTES AND TITLE

5.1 Transfer of waste will be considered complete when **SWS** or its designee signs a standard form of manifest indicating an acceptance of delivery of the Infectious Waste Material. At that time, title, risk of loss and all other incidents of ownership with respect to those Infectious Waste Materials shall be transferred from the **Generator** to **SWS.**

5.2 If, following signature of a manifest pertaining to **Generator's** Infectious Waste Material, such waste material is discovered to be "non-conforming" in whole or in part, **SWS** may revoke its acceptance of all such Infectious Waste Material. A revocation of acceptance shall operate to revert title, risk or loss, and all other incidents of ownership to **Generator** at the time revocation is communicated, either orally or in writing, to **Generator** and **Generator** shall

hold **SWS** harmless thereof. Infectious Waste Material shall be considered "non-conforming" for the purposes of this Agreement:

a. If it is not in accordance with the descriptions, limitations, or specifications stated in the Sure-Way Systems Infectious Waste Profile Sheet attached hereto as Exhibit A; or

b. If it contains constituents or components, not specifically identified in Sure-Way's Infectious Waste Material Profile Sheet with (1) increases the nature or extent of the hazard and risk undertaken by **SWS** in agreeing to handle, load, transport, store, treat or dispose of the Infectious Waste Material; or (2) cannot, for reasons relating to the designing or permitting of the facility, be stored, treated, or disposed of at the relevant waste management facility.

6. SURE-WAY WARRANTIES

6.1 **SWS**, or its designee, understands the currently known hazards which are presented to persons, property and the environment in the transportation, storage and disposal of the Infectious Waste Material;

6.2 **SWS**, or its designee, will transport, store and dispose of the Infectious Waste Material in full compliance with all State and Federal EPA regulations and other state and local laws and regulations.

6.3 The waste management facilities utilized are now licensed and permitted to store and dispose of waste materials within the description of the Infectious Waste Material

6.4 In the event such waste management facilities lose permitted status during the term of this Agreement, **SWS** will promptly notify **Generator** of such loss and take its waste to a secondary, properly licensed facility for disposal so as to not disrupt service to the **Generator.**

7. GENERATOR'S WARRANTIES

The **Generator** shall warrant conformance and compliance with the following conditions:

7.1 All material packed Sure-Way's containers conform to the descriptions of its Infectious Waste Material made in Section 1, and that the Sure-Way Infectious Waste Material Profile Sheet attached hereto as Exhibit A, is true and correct;

7.2 Infectious Waste Material transferred by **Generator** hereunder will be packaged in Sure-Way's patented sharps containers and suitably protected from damage until time of pick-up.

7.3 Hazards and risks known to or learned by **Generator** to be of incident to the handling, transportation, storage, treatment, and disposal of the Infectious

Waste Material are to be communicated to **SWS** in a timely fashion. They have been communicated, and will continue to be communicated during the term hereof.

7.4 If the Infectious Waste Material is, or contains, hazardous substances as defined pursuant to Section 101 of the Federal Comprehensive Environmental Response, Compensation and Liability Act of 1980 or any other Federal, State of local law or regulation, **Generator** will advise **SWS** or their designee of the load or Infectious Waste Material containing a reportable quantity of any hazardous substance or substance pursuant to Section 102 of said Act or other applicable law or regulation, specifying those hazardous substances present in a reportable quantity. If such hazardous materials cannot be stored, treated, or disposed of by **SWS**, **SWS** shall decline to accept and shall return said shipment.

7.5 If the Infectious Waste Material is covered by requirements of any state or local laws or regulations relating to hazardous wastes or hazardous materials, it will comply with all applicable requirements of such laws or regulations.

7.6 The **Generator** is responsible for any loss or damage to sharps container brackets, cabinets, or transport carts furnished and installed by Sure-Way in the **Generators** facility in the course of providing these services.

7.7 The Generator warrants and understands that the container usage given to Sure-Way for determining the volume of sharps waste produced at the facility is accurate and that if it is determined that faulty numbers were provided the contract **price will be adjusted to reflect the accurate volumes** and rest of the contract will remain if force as stated.

8. TERMINATION

8.1 This agreement may be cancelled by **SWS:**

A. If the **Generator** fails to pay its bill in a timely manner.
B. If the **Generator** ships or tenders material in violation of the Agreement; or;
C. If **SWS** loses permitted status.

8.2 This Agreement may be cancelled by the **Generator:**

A. If notice is given thirty (30) days prior to the termination date set forth in this agreement.
B. With or without cause with a 90 day notice.
C. For failure to perform by **SWS.**

8.3 Damage for improper termination shall not be more than the amount due under the remaining term of the Agreement or part thereof up to the next anniversary date of this agreement.

9. CONFIDENTIALITY

Each party shall treat this Agreement as confidential and not disclose to others during or subsequent to the term of this Agreement, except as is required by law or is necessary to properly perform this Agreement (and then only on a confidential basis satisfactory to the other party) any information regarding the Infectious Waste Material. Neither party shall make any news release, advertisement, or public announcement regarding the subject matter of this Agreement without the prior approval of the other party.

This validity, interpretation and performance of this Agreement shall be governed and constructed in accordance with the laws of the State of Montana and applicable federal laws and regulations.

10. AGREEMENT

This Agreement incorporates the entire understanding and agreement regarding the transportation, storage, and disposal of the Infectious Waste Material and supersedes any and all terms and conditions which may be contained in any purchase orders issued by **Generator** prior to or subsequent to this Agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

11. SERVICE COMMENCEMENT

Start up date for service will be for entire facility the billing start date is _____. Please sign below where indicated and return the original to Sure-Way Systems. This is a 3 year contract.

THIS PROPOSAL IS AGREED TO AND ACCEPTED BY:

Sure-Way Systems, Inc.		_____ **Facility**	
_____	_____	_____	_____
Authorized Signature	Date	Authorized Signature	Date
_____		_____	
Title		Title	

Sure-Way Systems, Inc.
Business Office Information

Frequency of Pick-Up:_____

Generator Information:

Mailing Address:_____

Billing Address:_____

Service Contact Person:_____ Title:_____

Phone:_____

Billing Contact Person:_____ Title:_____

Phone:_____

Price Per Location:_____

Number of Locations:_____

Exhibit RLS-16

PUBLICATIONS, by Robert L. Sheridan

1. Sheridan, Robert; User Fees: Should the Industry Oppose or Support? Medical Device & Diagnostic Industry, April 1993.

2. Sheridan, Robert; How to Manage Regulatory Submissions for Device Modifications. Medical Device & Diagnostic Industry, October 1993.

3. Sheridan, Robert, and Breslawec, Halnya; Managing Regulatory Submissions for Device Modifications (Revisited). Medical Device & Diagnostic Industry, July 1994.

4. Sheridan, Robert, and Breslawec, Halnya; 510(k) Changes: FDA Tries Again. Medical Device & Diagnostic Industry, December 1995.

5. Sheridan, Robert; Leadership and Reform: FDA's Ongoing Duty. Medical Device & Diagnostic Industry, August, 1996.

6. Sheridan, Robert: FDA's Evaluation of Clinical Utility. Regulatory Affairs Focus, Volume 2, Issue 11, November 1997