EXHIBIT GC-25

From: Snesko, Walter M. [WMS@CDRH.FDA.GOV]
Sent: Monday, July 25, 2005 11:30 AM
To: 'garywayyn@aol.com'
Subject: Reconditioners, Rebuilders, Reprocessors
Dear Mr. Chilcott,

The Food and Drug Administration does not regulate reconditioners, rebuilders, reprocessors of medical devices. Therefore they are not required to submit an Establishment Registration Form (Form 2891).
Reconditioners, rebuilders, reprocessors perform cosmetic work and or bring the device back to specifications of the original manufacturer, by putting in new components or reconditioned components, obtained from the original manufacturer or components identical in design, with same component specifications can be used in place of original component.
The reconditioners, rebuilders and reprocessors may recondition the components to be used in the same device to ensure the device continues to operate according to the devices original specifications.

Sincerely yours,

Walter Snesko
Division of Small Manufacturers, International and
Consumers Assistance,
Office of Communication, Education and Radiation
Programs
Center for Devices and Radiological Health
Phone: 301-443-6597, ext 120 or 1-800-638-2041
FAX: 301-443-8818
E-mail: WMS@CDRH.FDA.GOV
http://www.fda.gov/cdrh
Thank you

-----Original Message-----
From: h2oman [mailto:h2oman@fdn.com]
Sent: Friday, July 22, 2005 2:56 PM
To: WMS@CDRH.FDA.GOV
Subject: 510K REQUIREMENTS FOR HEMODIALYSIS

Dear Sir:

Thank you for your help today on the VA Hospital.

I am questioning law and or procedure for Hemodialysis centers on maintenance of there centers. If you could help me out with this problem I would be most thankful.

Clay Prentice
All Florida Water Inc.
h2oman@fdn.com