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MAY 28 1999

K991612

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STERILOGIC
WASTE SYSTEMS INC

510(k) SUMMARY

807.92(1)

COMPANY NAME:	STERILOGIC WASTE SYSTEMS, INC.
COMPANY ADDRESS:	9948 KISTLER VALLEY ROAD, SUITE 102 KEMPTON, PA 19529-0084
TELEPHONE: FAX:	(610) 756-3003 (610) 756-3004
CONTACT PERSON:	CALVIN A. ODHNER, V.P.
SUMMARY PREPARATION DATE:	May 6, 1999

807.92(2)

TRADE OR PROPRIETARY NAME:	STERISHARP™ 2.5-GALLON RSDC
COMMON NAME:	REUSABLE SHARPS DISPOSAL CONTAINER
CLASSIFICATION:	CLASS II – ACCESSORY DEVICE

807.92(3)

EQUIVALENT DEVICE (A):	GRAPHICS CONTROLS – POINT-OF-USE II SHARPS-A-GATOR MAIL-DROP TORTUROUS PATH TUMBLER LID (510[k] #K964387)
EQUIVALENT DEVICE (B):	ROTONICS MANUFACTURING, INC. (RMI) ROTATIONALLY MOLDED PLASTIC REUSABLE SHARPS CONTAINER (510[k] #K964026)

807.92(4)
DESCRIPTION:

REUSABLE PLASTIC SHARPS DISPOSAL CONTAINER; two components of the device include (a) a plastic mail-drop, torturous path tumbler lid (where needles and sharps waste is inserted) and (b) a rotationally molded plastic bottom (the container), leak-proof on four sides and bottom, where needles are dropped and stored until container unit is emptied and cleaned.

807.92(5)
INTENDED USE:

Reusable containers are intended to be used by healthcare providers (hospitals, laboratories, medical clinics, veterinary clinics, and other such areas and facilities where needles, sharps waste and other infectious waste is generated). The containers are designed to safely contain sharps waste prior to removal from generating facility and ultimate treatment and disposal of waste. Containers are of such a design and material as to withstand emptying, unloading, washing and disinfecting for reuse according to 49 CFR Sections 178.603, 173.4465(d), 173.465(e) and 178.608.

807.92(6)
LID: The Graphics Controls' lid will be used on the top of the container. This lid is approved in 510(k) #K964387.

CONTAINER: The bottom portion of the unit has the same technological characteristics and a similar design to the Rotonics Manufacturing Sharps Plus 5-Gallon Reusable Sharps Container, being made of the same process, material, densities and thickness. The only comparable changes are (1) the size of the container (reduced from 5 gallons to 2.5 gallons) and (2) the lid receiving channel, which was increased from 5/16" to 9/16" to accommodate the slightly larger rim that is present on the Graphic Controls lid.

The container is made from linear low-density polyethylene with a thickness of 0.125", rotationally molded (by building up layers of plastic).

807.92(6)(b) The SteriSharp™ 2.5 Gallon RSDC meets and exceeds the primary design characteristics needed to comply with the OSHA Bloodborne Pathogens Standard. Data for the following tests have been provided and are as follows:

Puncture	Health Devices 22	Needle penetration force	Pass
Vibration	49 CFR 178.608	1 hour repetitive bounce	Pass
Free Fall Drop	49 CFR 178.603	-18° C 5 drops 1.2 meter	Pass
Stacking	49 CFR 178.606	24 hrs. under 30 kg	Pass
Penetration	49 CFR 178.609(h)(1)	7 kg steel rod - 1 meter	Pass

"The package, as submitted and tested, visually appears to satisfy the test criteria and be capable of preventing the loss or dispersal of the contents for conditions normal to transport." (Container Testing Laboratory, Inc.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1999

Mr. Calvin A. Odhner
Vice President
Sterilogic Waste Systems, Incorporated
9948 Kistler Valley Road, Suite 102
PO Box 84
Kempton, Pennsylvania 19529

Re: K991612
Trade Name: SteriSharp™ 2.5 Gallon RSDC, Model #RSDC2.5G
Regulatory Class: II
Product Code: MMK
Dated: May 6, 1999
Received: May 10, 1999

Dear Mr. Odhner:

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

Page___of___

510(k) Number (if known): K991612

Device Name: STERISHARP™ 2.5 GALLON RSDC

Indications For Use:

The SteriSharp™ 2.5 Gallon RSDC reusable containers are intended to be used by healthcare providers (hospitals, laboratories, medical clinics, veterinary clinics, and other such areas and facilities where needles, sharps waste and other infectious waste is generated). The containers are designed to safely contain sharps waste prior to removal from generating facility and ultimate treatment and disposal of waste. Containers are of such a design and material as to withstand emptying, unloading, washing and disinfecting for reuse according to 49 CFR Sections 178.603, 173.4465(d), 173.465(e) and 178.608.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991612