K083511

FDA 510(k) Premarket Notification

MAR 6 2009

Industrial Water Solutions, Inc.
October 28, 2008

510(k) SUMMARY

807.92(a)(1)

COMPANY NAME:	Industrial Water Solutions, Inc.
COMPANY ADDRESS:	2692 Willowlawn Street Roanoke, Virginia 24018
TELEPHONE NUMBER: FACSIMILE NUMBER:	540/772-0599 540/772-7944
CONTACT PERSON:	Thomas P. Stewart
SUMMARY PREPARATION DATE:	November 24, 2008

807.92(a)(2)

TRADE or PROPRIETARY NAME:	Enviro Sharp Solutions 3
COMMON NAME:	Reusable Sharps Disposal Container
CLASSIFICATION:	Class II – Accessory Device

807.92(a)(3)

EQUIVALENT DEVICE #1:	Bemis Sharp Sentinal®
CONTAINER LID:	The Bemis Sharp Sentinal® container lid ("lid") is used on the top of the Enviro Sharp Solutions 3 container. This Bemis Sharp Sentinal® container lid has been approved under 510(k) #K953797.
EQUIVALENT DEVICE #2:	SteriSharp™ 3 Gallon RSDC (510(k) #K020664
CONTAINER BASE:	The bottom portion of the unit (the "container") is a reusable polyethylene cavity with a wall thickness of 0.125" ± 0.002" similar to that of the SteriSharp™ 3. The SteriSharp™ 3 container has been approved under 510(k) #K020664

807.92(a)(4)

DESCRIPTION:

The Enviro Sharp Solutions 3 is a reusable plastic sharps disposal container. It features a mail drop, torturous path tumbler lid for safe and easy disposal of sharps. Simply deposit syringes horizontally into the opening of the lid, and they are deposited automatically into the container. When the container is full, the tumbler will indicate that it is time to replace the unit. Just insert the locking tabs to secure the container in a closed position and replace it with a clean sanitized unit. Using our proprietary equipment, Sci-Med Waste employees will empty and sanitize the unit and return it to the facility to use for the next switch out. The durable high-density polyethylene construction of the Enviro Sharp Solutions 3 makes it leak-proof, puncture resistant and stable. It meets or exceeds all OSHA recommendations for sharps containers, and because it is reusable, it is more environmentally friendly and less expensive than disposable alternatives.

A label will be attached to the outside of the container specifying the intended use of the container. A sample of this label is attached at the end of this document. (See Attachment 1)

807.92(a)(5)

INTENDED USE:

The Enviro Sharp Solutions 3 reusable container is intended for use by healthcare providers, such as hospitals, laboratories, medical clinics, veterinary clinics and other facilities where needles, sharps waste and other infectious waste are generated. The containers are designed to safely contain sharps waste prior to removal from generating facility and until ultimate treatment and disposal of waste. Containers are of such a design and materials as to withstand emptying, unloading, washing and disinfecting for reuse according to 49 CFR §§ 178.603, 173.4465(d), 173465(e) and 178.608.

807.92(a)(6)

The Enviro Sharp Solutions 3 reusable container is substantially equivalent to the SteriSharp™ 3, and uses the Bemis Sharp Sentinal® (510k)#K953797 lid that is a semi-transparent natural colored polypropylene mail drop, torturous path tumbler lid. It is injection molded and varies in thickness from 0.05" to 0.07". The base container is similar in design and ergonomic characteristics to the SteriSharp™ 3. While the base of the SteriSharp™ 3 unit is manufactured using polypropylene, the Enviro Sharp Solutions 3 unit is manufactured with a thicker wall (0.125" ± 0.002" as compared to 0.06" ± 0.01") and stronger polymer (HDPE) to help confer reusable qualities.

COMPARISON TABLE (lid)	BEMIS SHARP SENTINAL®	NAME OF YOUR CONTAINER
Indications for use	Healthcare Sharps	Same
Target population	Healthcare Professionals	Same
Design	Torturous path, mail-drop	Same
Materials	Polypropylene	Same
Performance	Multiple Use	Same
Mechanical safety	Mail-drop	Same
Where used	Healthcare facilities/labs	Same
Standards met	49 CFR/HD 22 (multi-use)	Same

The Enviro Sharp Solutions 3 reusable container is also substantially equivalent to the SteriSharp™ 3 reusable container. They are both a combination of a polypropylene tumbler lid with a polyethylene base. The SteriSharp™ 3 base is a red, rotationally molded liner low density Polyethylene cavity, while the Enviro Sharp Solutions 3 is a red, injection molded high density polyethylene cavity.

COMPARISON TABLE (container)	SteriSharp™ 3	NAME OF YOUR CONTAINER
Indications for use	Healthcare Sharps	Same
Target population	Healthcare Professionals	Same
Design	Injection mold tapered	Same
Materials	HDPE	Same
Performance	Multiple Use	Same
Where used	Healthcare facilities/labs	Same
Standards met	49 CFR/HD 22	Same

807.92(b)(1)

Over a two-day period from November 4, 2008 to November 5, 2008, all components of a random sampling of the Enviro Sharp Solutions 3 container were subjected to a simulated life-use of 100 cycles of closing, filling, depositing waste, opening, emptying, washing and sanitizing. After simulated use, there were no visible signs of failure. Containers were then performance tested and passed. (See below.)

807.92(b)(2) and (3)

The Enviro Sharp Solutions 3 meets and exceeds the primary design characteristics needed to comply with the OSHA Blood borne Pathogens Standard. Date for the following tests have been provided and are as follows:

Puncture	**Health Devices 22**	**Needle penetration force**	**Pass**
Leak Resistance	**Health Devices 22**	**24 Hours filled with water**	**Pass**
Vibration	**49 CFR 178.608**	**1 hour repetition bounce**	**Pass**
Free Fall Drop	**49 CFR 178.603**	**5 drops 3.9 feet**	**Pass**
Stacking	**49 CFR 178.606**	**24 hours under 65 lbs.**	**Pass**

"The package, as submitted and tested, visually appears to satisfy the test criteria and is capable of preventing the loss or dispersal of the contents for conditions normal to transport" (Container Testing Laboratory, Inc.) (See Attachment 2)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 6 2009

Mr. Tom Stewart
Industrial Water Solutions, Incorporated
2692 Willowlawn Street
Roanoke, Virginia 24018

Re: K083511
Trade/Device Name: Enviro Sharp Solution 3
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: January 15, 2009
Received: February 11, 2009

Dear Mr. Stewart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K083511

Device Name: Enviro Sharp Solutions 3

Indication For Use:

The container is intended for use by healthcare providers, such as hospitals, laboratories, medical clinics, veterinary clinics and other facilities where needles are generated. The container is designed to safely contain sharps prior to removal from the generating facility, during transportation and until ultimate treatment and disposal of the sharps.

Prescription Use _____ And/Or Over the Counter Use ____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083511