K090157

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

MAY - 4 2009

Re: Isolyser SMSm Traditional 510(k)
WCM Waste and Compliance Management, Inc.
Carlsbad, CA 92011

510(k) Summary

Owner of Device
WCM Waste & Compliance Management, Inc.
6054 Corte Del Cedro
Carlsbad, CA 92009-1514

Contact
Sara Beth Watson
Steptoe & Johnson LLP
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Washington, DC 20036
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Date Prepared
January 15, 2009

Name of Device

Common Name:	Sharps Container
Proprietary Name:	Isolyser SMSm: Home Sharps Management (HSM) 800m; Sharps Management System (SMS) 2400m; Sharps Management System (SMS) 4000m; Sharps Management System (SMS) 10000m; and Sharps Management System (SMS) 5.3m.
Establishment Registration Number:	2032810 (2008)
Classification Name:	Accessory to hypodermic single lumen needles
Regulation:	880.5570
Classification:	Class II
Product Code:	MMK
Panel:	General Hospital

Device Uses and Description

The Isolyser Home Sharps Management (HSM) 800m; Sharps Management System (SMS) 2400m; Sharps Management System (SMS) 4000m; Sharps Management System (SMS) 10000m are disposable non-reusable sharps containers that are intended to provide for safe and effective disposal of medical sharps and/or medical/red-bag wastes. The Isolyser Sharps Management System (SMS) 5.3m is intended only for the storage and disposal of filled approved sharps containers and/or medical/red-bag wastes. The SMS 5.3m is not intended for the direct disposal of used medical sharps. The HSM 800m, SMS 2400m, SMS 4000m, SMS 10000m, and SMS 5.3m are marketed for home use by home healthcare providers and for use in the offices, exam, and patient rooms of small quantity generators such as medical doctors, dentists, veterinarians, and laboratories.

The SMSm container is stable, closable, puncture resistant (SMS 5.3m not tested) and leak-proof on the sides and bottom. Used medical sharps and/or medical/red-bag wastes are placed vertically into the opening on the top of the container. Once placed into the container, the SMSm does not require users to reach by hand into the container to retrieve contaminated sharps and/or medical/red-bag wastes. Once the container is full, the SMSm is intended to be mailed back to WCM Waste and Compliance Management, Inc. for proper disposal. The overall design and specifications for the Isolyser SMSm meet OSHA Bloodborne Pathogens Standard as well as the American Society for Testing and Materials Standard F2132-01(2008) (SMS 5.3m not tested). All SMSm containers have BIOHAZARD warning labels clearly visible with lettering in contrasting color and are affixed by adhesives to the sides of the SMSm container.

Predicate Devices

The Isolyser SMSm sharps containers are substantially equivalent in intended use, function and basic composition to the Isolyser SMS sharps containers approved in 510(k) K943626 and Sharps Compliance, Inc.'s Sharps Disposal by Mail System 15000 [510(k) unknown]. Specifically, the HSM 800m, SMS 2400m, SMS 4000m, and SMS 10000m have identical technological characteristics to the Isolyser SMS containers approved in 510(k) K943626; the containers are identical in size, composition, and design. In contrast to the Isolyser SMS approved in 510(k) K943626, the Isolyser SMSm is marketed as an empty container and does not contain the ingredients necessary to create a polymer to encapsulate used medical sharps. The SMS 5.3m has technological characteristics similar to Sharp Compliance, Inc.'s Sharps Disposal by Mail 15000. Both containers are closable plastic 5-gallon receptacles intended for the disposal of filled approved sharps containers and/or medical/red-bag wastes. The SMS 5.3m and the Sharps Disposal by Mail 15000 are not intended for the direct disposal of used medical sharps. Once filled, the Isolyser SMSm containers are mailed to WCM Waste and Compliance Management, Inc. for proper disposal. This disposal is substantially equivalent to Sharps Compliance, Inc.'s Sharps Disposal By Mail System.

Conclusion

The Isolyser SMSm is substantially equivalent to the predicate devices based on the descriptive data, compliance with standards, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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WCM Waste & Compliance Management, Incorporated
C/o Ms. Sara Beth Watson
Attorney
Steptoe & Johnson LLP
1330 Connecticut Avenue, NW
Washington, District of Columbia 20036

Re: K090157
Trade/Device Name: Isolyser SMSm Sharps Containers, Including Models: Home Sharps Management (HSM) 800m; Sharps Management System (SMS) 2400m; Sharps Management System (SMS) 4000m; Sharps Management System (SMS) 10000m, and Sharps Sharps Management System (SMS) 5.3m.
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: April 9, 2009
Received: April 10, 2009

Dear Ms. Watson:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090157

Device Name: Isolyser SMSm Sharps Containers, including models: Home Sharps Management (HSM) 800m; Sharps Management System (SMS) 2400m; Sharps Management System (SMS) 4000m; Sharps Management System (SMS) 10000m, and Sharps Management System (SMS) 5.3m.

Indications For Use: The Isolyser Sharps Management Systems SMSm is a single-use, disposable, over-the-counter sharps container intended for use in clinical and non-clinical settings for the disposal of contaminated sharps and/or medical/red-bag wastes. The SMSm is marketed in five (5) different models: (1) Home Sharps Management (HSM) 800m, .98 liters, 3.45 x 2.72 x 7.29 (in.); (2) Sharps Management System (SMS) 2400m, 3.3 liters, 5 x 5x 10 (in.); (3) Sharps Management System (SMS) 4000m, 5.97 liters, 8.47 x 5.99 x 8.87 (in.); (4) Sharps Management System (SMS) 10000m, 10.47 liters, 8.51 x 5.99 x 14.32 (in.); and (5) Sharps Management System (SMS) 5.3m, 21.1 liters, 11.93 x 9.87 x 14.68 (in.). Each SMSm model is designed to safely and securely contain used medical sharps and/or medical/red-bag wastes prior to removal and subsequent disposal. The SMS 5.3m is intended only for the storage and disposal of filled approved sharps containers and/or medical/red-bag wastes. Once an empty SMSm container has been filled with used medical sharps and/or medical/red-bag wastes, the entire SMSm container is intended to be packaged and mailed-back to WCM Waste and Compliance Management, Inc. for proper disposal. The HSM 800m, SMS 2400m, SMS 4000m, SMS 10000m, and SMS 5.3m are intended for home use by home health care providers and for use by small quantity health care providers such as dentists, medical doctors, veterinarians, and laboratories. The SMSm sharps containers are not intended for reuse.

Charles P. Murphy MD

ivision Sign-Off)
vision of Anesthesiology, General Hospital
ection Control, Dental Devices

0(k) Number: K090157

Prescription Use _____ **AND/OR** **Over-The-Counter Use** X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)