K083129

510(k) Summary

Submitted by Sharps Compliance, Inc.
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Houston, Texas 77054
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Contact Name: Al Aladwani, Senior Vice President of Operations

DEC 15 2008

Date Submitted: December 4, 2008

Trade Name: Sharps Compliance Container
Common Name: Sharps Container

Product Code / Regulation: MMK / 21 C.F.R. 880.5570

Description: The Sharps Compliance Container is a sharps container (disposable infectious waste container) in 1 gallon, 2 gallon and 3 gallon sizes designed to meet Occupational Safety and Health Administration ("OSHA") regulations on bloodborne pathogens (29 C.F.R. 1910.1030).

Intended Use: The Sharps Compliance Container is a disposable infectious waste container in 1 gallon, 2 gallon and 3 gallon sizes, intended for use by laypersons or health professionals, in small usage areas in clinical and non-clinical settings, such as: phlebotomy, nursing homes, homes, isolation, doctors office, clinics, labs, or school nurses office. The Sharps Compliance Container is eventually disposed of through a mail-back system or otherwise in accordance with local regulations.

Substantial Equivalence: The Sharps Compliance Container is similar in design and intended use to the Sage 2 Gallon Alternate Care Sharps Container (K973911). Substantial equivalence to the predicate device was evaluated according to the criteria identified in the FDA guidance document "Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers," issued in October 1993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Al Aladwani
Senior Vice President of Operations
Sharps Compliance, Incorporated
9220 Kirby Drive, Suite 500
Houston, Texas 77054

DEC 15 2008

Re: K083129
Trade/Device Name: Sharps Compliance Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: December 4, 2008
Received: December 5, 2008

Dear Mr. Aladwani:

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,

Chiu Lin, Ph.D.
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): K083129

Device Name: Sharps Compliance Container

Intended Use:

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

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

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