

K083129

### 510(k) Summary

**Submitted by** Sharps Compliance, Inc.

**Address:** 9220 Kirby Drive, Suite 500,  
Houston, Texas 77054

DEC 15 2008

**Telephone:** (800) 772-5657 or (713) 432-0300

**Facsimile:** (713) 660-3586

**Contact Name:** Al Aladwani, Senior Vice President of Operations

**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.



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:

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.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

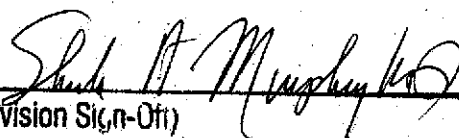
AND/OR

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

Page 1 of 1

4-2

510(k) Number: K083129