510(k) SUMMARY

510(k) Notification K132007

GENERAL INFORMATION

Applicant:
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Lake Forest, IL 60045
U.S.A.
Phone: 847-943-6658
FAX: 800-593-5085

Contact Person:
Lori Adels, PhD
Regulatory Consultant
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U.S.A.
Phone: 408-400-0856
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Date Prepared: December 27, 2013

DEVICE INFORMATION

Trade Name:
Stericycle Sharps Management Service Reusable Sharps Container

Generic/Common Name:
Container, Sharps

Classification:
21 CFR§880.5570, Hypodermic single lumen needle.
Class II

Product Code:
MMK

510(k) SUMMARY

PREDICATE DEVICE

- Daniels Sharpsmart™ reusable sharps container (K001337)

INTENDED USE

The Stericycle Sharps Management Service Reusable Sharps Container is intended for use in health care facilities for the storage and transport for disposal of syringes and other medical sharps waste.

The Stericycle Sharps Management Service Reusable Sharps Container is available in the following configurations:

- 2 gallon: 6.9" x 12.3" x 13.9", Red or Yellow color
- 4 gallon: 6.9" x 12.3" x 21.9", Red or Yellow color

PRODUCT DESCRIPTION

The Stericycle Sharps Management Service Reusable Sharps Container is a single piece, reusable, sharps container that is intended to be used in health care facilities where medical sharps waste is generated. The container is injection molded of polypropylene copolymer with a uniform nominal thickness of 0.125". The container is available in 2 and 4 gallon sizes and in red or yellow color. The lid of the container is constructed so that the sharps waste is disposed safely and effectively by gravitational force when the waste is placed in the inner tray. The Stericycle Sharps Containers utilize a counterbalanced lid design that acts as a protective barrier to keep sharps objects within the container from coming back up through the lid and anyone from reaching into the container to retrieve sharps waste.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Stericycle Sharps Management Service Reusable Sharps Container are similar to the predicate device. Performance data are provided to support the determination of substantial equivalence.

SUBSTANTIAL EQUIVALENCE

The intended use for the predicate device is substantially equivalent to the proposed intended use of the Stericycle Sharps Management Service Reusable Sharps Container. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Stericycle Sharps Management Service Reusable Sharps Container is substantially equivalent to the predicate device. Details are provided in the following table.

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Feature	Stericycle Sharps Management Service Reusable Sharps Container	Daniels Sharpsmart™ reusable sharps container
510(k) Number	K132007	K001337
Indications for Use	Stericycle Sharps Management Service Reusable Sharps Container is intended for use in health care facilities for the storage and transport for disposal of syringes and other medical sharps waste.	Reusable containers intended to be used for the disposal of contaminated medical sharps in health care facilities.
Classification/ Product Code	MMK	MMK
Regulation Number	21 CFR§880.5570, Hypodermic single lumen needle	21 CFR§880.5570, Hypodermic single lumen needle
Container Material	Polypropylene copolymer	Polypropylene copolymer
Material Thickness	0.125" (nominal)	Not available
Volume (Fill Capacity)	2 gallons 4 gallons	S14: 7.0 quarts (1.8 gallons) S22: 15.5 quarts (3.9 gallons) S32: 25.0 quarts (6.3 gallons)
Dimensions (L x W x H)	2 Gallon: 12.3" x 6.9" x 13.9" 4 Gallon: 12.3" x 6.9" x 21.9"	S14: 13.5" x 6.6" x 11.0" S22: 13.5" x 6.6" x 17.3"
Intended Location of Use	Health care facilities	Health care facilities
Biohazard Waning Label	Labeled as Biohazard in Fluorescent orange or orange-red with lettering in contrasting color	Labeled as Biohazard in Fluorescent orange or orange-red with lettering in contrasting color
Sharps access and closure	Gravity-activated	Gravity-activated
Closable	Yes	Yes
Puncture Resistant	Yes [Test method: ASTM F2132-01 (2008)]	Information not available.
Leakproof on Sides and Bottom	Yes	Yes
Impact Resistant	Yes	Yes
Vibration Resistant	Yes	Yes
Stacking Resistant	Yes	Yes
Capable of maintaining stable, upright position	Yes	Yes
No feature to bend, break, or shear needles	No feature	No feature
Unwinders	No feature that would recap, remove, or unwind needle of the hub.	No feature that would recap, remove, or unwind needle of the hub.
Reusable or Non-reusable Container	Reusable	Reusable

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Feature	Stericycle Sharps Management Service Reusable Sharps Container	Daniels Sharpsmart™ reusable sharps container
Performance Standards	• American Society for Testing and Materials (ASTM) Consensus Standards for Puncture Resistance (ASTM F2132-01:2008) • Australian/New Zealand Standard for Reusable containers for collection of sharp items (AS/NZS 4261:1994) • Department of Transportation (DOT) regulations (49 CFR 173.197) • Occupational Safety and Health Administration (OSHA) bloodborne pathogen standards (29 CFR 1910.1030)	• Australian/New Zealand Standard for Reusable containers for collection of sharp items (AS/NZS 4261:1994) • Department of Transportation (DOT) regulations (49 CFR 173.197) • Occupational Safety and Health Administration (OSHA) bloodborne pathogen standards (29 CFR 1910.1030)
Features for safe transport and re-use	• Secure closure and puncture resistance for transport • Container is permanently marked for reuse • Container is disinfected by Stericycle prior to reuse • Container volume is between 2 and 40 gallons in volume (49 CFR 173.197)	• Secure closure and puncture resistance for transport • Container is permanently marked for reuse • Container is disinfected prior to reuse • Container volume is between 2 and 40 gallons in volume (49 CFR 173.197)

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TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

The FDA has not established a performance standard for this product under Section 514. However, the Stericycle Sharps Management Service Reusable Sharps Container complies with criteria identified in FDA guidance documents, Occupational Safety and Health Administration (OSHA) standards on blood borne pathogens, as outlined in 29 CFR 1910.1030, Department of Transportation (DOT) regulations controlling the transport of regulated medical waste as outlined in 49 CFR 173.197, and has passed non-clinical performance testing as summarized in the table below.

Testing Type (each test performed on both 2- and 4-gallon Container sizes)	**Test Standard / Description**	**Result**
Life–cycle testing	Subsequent to conditioning of units representative of reprocessing and transport of the 2- and 4-gallon Reusable Sharps Containers, the units were tested and evaluated for the following parameters:	
• Vibration Resistance	ISTA 3E	Pass
• Impact Resistance	The filled container maintains its integrity when dropped 4 ft. to a concrete surface and retains its solid contents.	Pass
• Leak Resistance	The container loses no liquid over a 24-hour period.	Pass
• Needle Puncture Resistance	ASTM F2132-01:2008	Pass
DOT Vibration Resistance	49 CFR 178.608	Pass
DOT Impact Resistance	49 CFR 178.603	Pass
DOT Stacking Resistance	49 CFR 178.606	Pass
Topple Resistance	AS/NZS 4261:1994, Appendix D	Pass

The collective results of the performance testing demonstrate that the Stericycle Sharps Management Service Reusable Sharps Container meets the established specifications necessary for consistent performance of its intended use throughout its planned lifetime and is substantially equivalent to the predicate device.

CONCLUSION

The Stericycle Sharps Management Service Reusable Sharps Container shares its design and mechanism of action with the identified predicate device. The results of the bench testing confirm that the Stericycle Sharps Management Service Reusable Sharps Container functions to its specifications, performs as intended, and exhibits the appropriate characteristics of a sharps container. The Stericycle Sharps Management Service Reusable Sharps Container is substantially equivalent to the predicate device in terms of technological characteristics, intended use, and performance. No new issues of safety or effectiveness are raised by the Stericycle Sharps Management Service Reusable Sharps Container.

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SUMMARY

The Stericycle Sharps Management Service Reusable Sharps Container is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 27, 2013

Experien Group, LLC
C/O Dr. Ms. Lori Adels
Regulatory Consultant
Stericycle, Incorporated
755 North Mathilda Avenue, Suite 100
SUNNYVALE CA 94085

Re: K132007
Trade/Device Name: Stericycle Sharps Management Service Reusable Sharps Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: December 3, 2013
Received: December 4, 2013

Dear Dr Adels:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132007

Device Name
Stericycle Sharps Management Service Reusable Sharps Container

Indications for Use *(Describe)*

The Stericycle Sharps Management Service Reusable Sharps Container is intended for use in health care facilities for the storage and transport for disposal of syringes and other medical sharps waste.

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Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=200054049, cn=Sreekanth Gutala -S
Date: 2013.12.26 14:48:34 -05'00'