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510(k) Summary

Daniels Sharpsmart, Inc.
Ecoship Disposable Sharps Container
K132792

December 30, 2013

ADMINISTRATIVE INFORMATION

Manufacturer Name	Daniels Sharpsmart, Inc. 111 W Jackson Blvd., Suite 720 Chicago, IL 60604 Telephone: +1 (312) 546-8925 Fax: +1 (312) 276-4714
Official Contact	Alan Larosee Director of Compliance
Representative/Consultant	Allison C. Komiyama, Ph.D. Floyd G. Larson PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: akomiyama@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Ecoship Disposable Sharps Container
Common Name	Container, sharps
Classification Name	Hypodermic single lumen needle
Classification Regulations	21 CFR 880.5570, Class II
Product Code	MMK
Classification Panel	General Hospital
Reviewing Branch	Infection Control Devices Branch

INTENDED USE

Ecoship Disposable Sharps Container is intended to be used in healthcare facilities, including nursing stations, medication carts, laboratories, dental offices, emergency rooms, surgical rooms, treatment rooms, emergency vehicles, veterinarian offices and other small quantity waste generators for the safe disposal of hazardous sharps. The single-use device is intended for "Over-the-Counter" use. The container is eventually disposed of through a mail-back system or otherwise in accordance with local regulations. The manufacturer's bracket is required if the device is used on medication carts or in emergency vehicles.

DEVICE DESCRIPTION

Ecoship Disposable Sharps Containers are single-use sharps containers designed for point-first disposal of sharps. The containers are intended for over-the-counter use for the safe disposal of sharps, i.e. articles that can penetrate human skin. This definition includes, but is not limited to needles, scalpels, syringes with needles, disposable scissors, suture needles, stylets, trocars and broken test tubes. The containers are intended to be used in supervised areas of human and veterinary healthcare facilities. These areas may include nursing stations, laboratories, dental offices, physician offices, clinics, emergency rooms, surgical rooms, treatment rooms, research facilities, veterinarian practices and other small quantity waste generators. The devices are also intended to be used in healthcare facility mail-back programs and in home healthcare by clinical staff.

Two Ecoship Disposable Sharps Container models are described in this submission:

- D2-ES is 2 liters with fill capacity of 1.5 liters
  - Tare: 192 grams (6.77 oz)
  - Dimensions: (L) 142 mm x (W) 142 mm x (H) 151 mm
- D4-ES is 4 liters with fill capacity of 3 liters
  - Tare: 304 grams (10.72 oz)
  - Dimensions: (L) 142 mm x (W) 142 mm x (H) 303 mm

EQUIVALENCE TO MARKETED DEVICE

Daniels Sharpsmart, Inc. Ecoship Disposable Sharps Container is substantially equivalent in indications and design principles to the following predicate devices:

- Daniels Corporation PTY, INC., Sharpsmart S2 Disposable Sharps Container (K091736)
- Sharps Compliance, Inc., Sharps Compliance Container (K083129)
- Oak Ridge Products L.L.C., Oak Ridge Products Sharps Containers (K130281)

The D2-ES (2 liter) and D4-ES (4 liter) Ecoship Disposable Sharps Containers have a similar design and dimensions, use similar materials, and are similar in color to those cleared under K091736, K083129 and K130281. The subject device has similar fill capacity and locking

mechanisms to those cleared in K091736 and K130281. The access opening is similar in size and shape to K091736 and K083129. A return mail-back carton is provided similar to K083129.

No FDA performance standards for Ecoship Disposable Sharps Container have been established. The following tests were performed to ensure that the performance of the subject device meets Daniels Sharpsmart, Inc. requirements.

Pucture Resistance (per CSA Z316.6-07 *Evaluation of single-use and reusable medical sharps containers for biohazardous and cytotoxic waste)*

Needle puncture resistance was measured by taking various sections of a container and subjecting them to penetration with a 0.8 mm diameter needle. The force required to puncture the container was measured. The puncture resistance of each section of the container was greater than 20 N and the passing criterion was met.

Toppling Resistance (per CSA Z316.6-07 *Evaluation of single-use and reusable medical sharps containers for biohazardous and cytotoxic waste)*

Toppling resistance was measured by filling a container to nominal capacity with representative sharps material with a bulk density of 0.2 kg/liter and tilting it to a 15° angle. The container remained standing after being tilted, and the passing criterion was met.

Toppling Resistance (per ISO 23907 *Sharps injury protection – Requirements and test methods – Sharps containers)*

Toppling resistance was measured by filling a container to nominal capacity with representative sharps material with a bulk density of 0.2 kg/liter and tilting it to a 15° angle using the worst case challenge configurations. The container did not slide, and remained standing after being tilted, and the passing criteria were met.

Impact Resistance (per CSA Z316.6-07 *Evaluation of single-use and reusable medical sharps containers for biohazardous and cytotoxic waste)*

Impact resistance was measured by filling five containers to nominal capacity with representative sharps material with a bulk density of 0.2 kg/liter and surfactant solution equal to 6% of the nominal capacity. The containers were then conditioned at 23°C and dropped in a specific orientation from a height of no less than 1 meter. The containers did not rupture, tear, crack, open, or leak, and the passing criteria were met.

Cold Impact Resistance (per CSA Z316.6-07 *Evaluation of single-use and reusable medical sharps containers for biohazardous and cytotoxic waste)*

Cold impact resistance was measured by filling five containers with representative sharps material with a bulk density of 0.2 kg/liter. The containers were then conditioned at -18°C and dropped in a specific orientation from a height of no less than 1.2 meters. The containers did not rupture, tear, crack, open, or leak, and the passing criteria were met.

Handle Strength (per CSA Z316.6-07 *Evaluation of single-use and reusable medical sharps containers for biohazardous and cytotoxic waste)*

Handle strength was measured by filling a container to nominal capacity with material with a bulk density of 1 kg/liter and suspending it from the handle for 1 hour. The container remained intact and the handle did not rupture, tear, crack, or separate from the container. Therefore, the passing criteria were met.

Drop Test (per *United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations, Part 6, "Requirements For the construction and testing of packagings, intermediate bulk containers (IBCs), large packagings and portable tanks*)

This test was performed by filling six containers with no less than 1.2 kg of polycarbonate granules to a minimum of 95% capacity and prepared as they would be used in transport. The containers were then conditioned at -18°C and dropped in one of two specific orientations from a height of no less than 1.2 meters. The containers were not damaged, and the passing criterion was met.

Stacking Test (per *United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations, Part 6, "Requirements For the construction and testing of packagings, intermediate bulk containers (IBCs), large packagings and portable tanks*)

This test was performed by stacking three empty containers and prepared as they would be used in transport. A mass of 81 kg was then applied to the top of the stack for 24 hours at room temperature. The containers were not damaged, and the passing criterion was met.

Vibration Test (per 49 CFR Part 178.608 *Specifications for Packagings – Vibration Standard*)

This test was performed by filling three containers with polycarbonate granules to a minimum of 95% capacity, prepared as they would be used in transport. The containers were then vibrated (25 mm peak to peak at a frequency that induces displacement of 1.6 mm from the vibration plate) for 60 minutes at room temperature. The containers did not rupture, leak or deteriorate, and the passing criteria were met.

All testing demonstrated that the subject device is safe and effective for its intended use.

The devices conform to regulations per US OSHA 29 CFR 1910.1030 *Bloodborne Pathogens.*

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include engineering analysis and dimensional analysis.

Clinical data were not submitted in this premarket notification.

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including fill capacity and access opening size. The subject and predicate devices are packaged in similar materials. Any differences in the technological characteristics do not raise new issues of safety or efficacy. The device is safe and effective for its intended use and performs as well as or better than the predicate devices.

Overall, the Ecoship Disposable Sharps Container has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging.

Therefore, the information provided within the 510(k) is sufficient to demonstrate that the subject device is substantially equivalent to the predicates.

Summary: Table of Substantial Equivalence

	Subject Device	Predicate Devices		
	Ecoship Disposable Sharps Container Daniels Sharpsmart, Inc.	Sharpsmart™ S2 Disposable Sharps Container Daniels Corporation PTY, INC. K091736	Sharps Compliance Container Sharps Compliance, Inc. K083129	Oak Ridge Products Sharps Containers Oak Ridge Products L.L.C. K130281
Indications for Use	Ecoship Disposable Sharps Container is intended to be used in healthcare facilities, including nursing stations, medication carts, laboratories, dental offices, emergency rooms, surgical rooms, treatment rooms, emergency vehicles, veterinarian offices and other small quantity waste generators for the safe disposal of hazardous sharps. The device is intended for "Over-the-Counter" use. The container is eventually disposed of through a mail-back system or otherwise in accordance with local regulations.	Sharpsmart™ S2 disposable sharps container are intended to be used in healthcare facilities, including nursing stations, medication carts, laboratories, dental offices, emergency rooms, surgical rooms, treatment rooms, emergency vehicles, veterinarian office and other small quantity waste generators for the safe disposal of hazardous sharps. This device is intended for "Over-the-Counter" use. Physical Attributes: S2 model is a 1 quart size. The container has a volume of 1.6 quarts, fill capacity of 1.16 quarts and an empty weight of 0.95 lb. S2 model Color - Red with translucent lid or yellow with translucent lid. S2 model outer dimensions of 7.50 "h x 4.50"w x 5.50 "d. (190mm x 115mm x 140mm).	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.	Oak Ridge Products Sharps containers are single-use, disposable, non-sterile containers intended to be used for healthcare purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets, and blood needles. The target population is for trained healthcare professionals. The 1 quart Phlebotomy container is intended to be used with an appropriate mounting device. The 5.4 quart is intended to be used with an appropriate mounting device. The 2 gallon container is intended to be used in areas where there is no unsupervised patient access.

	Subject Device	Predicate Devices		
	Ecoship Disposable Sharps Container Daniels Sharpsmart, Inc.	Daniels S2 Disposable Sharps Container The Daniels Corporation K091736	Sharps Compliance Container Sharps Compliance, Inc. K083129	Oak Ridge Products Sharps Containers Oak Ridge Products L.L.C. K130281
Size (model)	2 liter (D2-ES) 4 liter (D4-ES)	1.6 quart (S2)	1 gallon 2 gallon 3 gallon	1 quart (Phlebotomy red) 5.4 quart (Universal clear) 5.4 quart (Universal red) 2 gallon (Nestable red)
Material	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Color of base	Red	Red or yellow	Red	Red or clear
Fill Line Capacity	1.5 liters (D2-ES) 3 liters (D4-ES)	1.51 liters (1.6 quarts)	3.79 liters (1 gallon) 7.57 liters (2 gallon) 11.36 liters (3 gallon)	0.76 liters (1 quart) 4.07 liters (5.4 quart) 6.8 liters (2 gallon)
Size (mm) L x W x H	142 x 142 x 151 (D2-ES) 142 x 142 x 303 (D4-ES)	190 x 115 x 140	222 x 140 x 178 (1 gal) 222 x 140 x 273 (2 gal) 222 x 140 x 426 (3 gal)	115 x 115 x 190 (1 quart) 280 x 115 x 267 (5.4 quart) 262 x 178 x 257 (2 gallon)
Container closure	Screw-on cap	Hinged friction fit door	Snap-on cap	Slide or rotating door
Locking mechanism	Yes	Yes	No	Yes
Access opening size	45 mm (diameter)	31.75 mm (diameter)	Unknown	50.8 x 38.1 mm 203.1 x 35.6 mm 142.2 x 58.4 mm
Needle Removal Mechanism	No	Yes	No	No
Brackets	Available but not necessary for use	Available but not necessary for use	Not available	Available and necessary for 1 quart and 5.4 quart models
Return shipping provided	Yes	No	Yes	No

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

January 31, 2014

Daniels Sharpsmart, Incorporated
Dr. Allison Komiyama
Senior Regulatory Specialist
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, CA 92130

Re: K132792
Trade/Device Name: Ecoship Disposable Sharps Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single-Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: December 30, 2013
Received: December 31, 2013

Dear Dr. Komiyama:

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,

Kwame O. Ulmer -S

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

Indications for Use

510(k) Number: K132792

Device Name: Ecoship Disposable Sharps Container
Model D2-ES: 2 liters with fill capacity of 1.5 liters
Model D4-ES: 4 liters with fill capacity of 3 liters

Indications:

Ecoship Disposable Sharps Container is intended to be used in healthcare facilities, including nursing stations, medication carts, laboratories, dental offices, emergency rooms, surgical rooms, treatment rooms, emergency vehicles, veterinarian offices and other small quantity waste generators for the safe disposal of hazardous sharps. The single-use device is intended for "Over-the-Counter" use. The container is eventually disposed of through a mail-back system or otherwise in accordance with local regulations. The manufacturer's bracket is required if the device is used on medication carts or in emergency vehicles.

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)

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
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