



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Snyder Industries, Inc.  
% Claudia Fell  
Regulatory Affairs  
Paxmed International, LLC  
12264 El Camino Real, Suite 400  
San Diego, California 92130

August 4, 2016

Re: K153274

Trade/Device Name: Med-tainer Single Deposit Container (SDC)  
Regulation Number: 21 CFR 880.5570  
Regulation Name: Hypodermic Single Lumen Needle  
Regulatory Class: Class II  
Product Code: MMK  
Dated: July 6, 2016  
Received: July 7, 2016

Dear Claudia Fell:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

A handwritten signature in black ink that reads "Susan Runno DDS, MA". The signature is written in a cursive style. In the background, there is a faint, semi-transparent logo for the FDA (U.S. Food and Drug Administration).

Tina Kiang  
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 (if known)  
K153274

Device Name  
Med-Tainer Single Deposit Container (SDC)

Indications for Use (Describe)

Med-Tainer Single Deposit Containers (SDC) are intended for the safe collection and transport of medical sharps. The reusable 10 gallon and 17 gallon containers are to be used in supervised areas of healthcare institutions such as hospitals, clinics, veterinary offices and laboratories.

Med-Tainer Single Deposit Containers			
Med-Tainer Single Deposit Container (SDC) 10 Gallon			
Model Number	Description	Approximate Size (inches)	
780300E74100	Med-Tainer SDC, 10 gallon, Red	18 L x 13 W x 16 H	
780300E74200	Med-Tainer SDC, 10 gallon, Teal	18 L x 13 W x 16 H	
780300E74300	Med-Tainer SDC, 10 gallon, Yellow	18 L x 13 W x 16 H	
780300E74400	Med-Tainer SDC, 10 gallon, Blue	18 L x 13 W x 16 H	
780300E74500	Med-Tainer SDC, 10 gallon, Green	18 L x 13 W x 16 H	
Med-Tainer Single Deposit Container (SDC) 17 Gallon			
Model Number	Description	Approximate Size (inches)	
780310E74100	Med-Tainer SDC, 17 gallon, Red	18 L x 13 W x 25 H	
780310E74200	Med-Tainer SDC, 17 gallon, Teal	18 L x 13 W x 25 H	
780310E74300	Med-Tainer SDC, 17 gallon, Yellow	18 L x 13 W x 25 H	
780310E74400	Med-Tainer SDC, 17 gallon, Blue	18 L x 13 W x 25 H	
780310E74500	Med-Tainer SDC, 17 gallon, Green	18 L x 13 W x 25 H	
Med-Tainer Single Deposit Container Lids			
Model Number	Description	Approximate Size (Inches)	Aperture (inches)
34300474	Locking Transport Lid, Black	17 L x 11 W	No opening – use to seal container for transport
34300476	Large Lab Lid, Black	17 L x 11 W	5.75 x 9.75 – use only in areas that have no unsupervised patient access
34300477	Small Lab Lid, Black	13 L x 9 W	No opening – use to cover large lab lid when not in use
78033300E74101	Restrictive Lid, Red	18.75 L x 13.5 W x 11.6 H	3.8 H x 13.8 W
78033300E74201	Restrictive Lid, Teal	18.75 L x 13.5 W x 11.6 H	3.8 H x 13.8 W
78033300E74301	Restrictive Lid, Yellow	18.75 L x 13.5 W x 11.6 H	3.8 H x 13.8 W
78033300E74401	Restrictive Lid, Blue	18.75 L x 13.5 W x 11.6 H	3.8 H x 13.8 W
78033300E74501	Restrictive Lid, Green	18.75 L x 13.5 W x 11.6 H	3.8 H x 13.8 W

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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**510(k) Summary**  
**Snyder Industries, Inc.**

**Med-Tainer Single Deposit Container (SDC)**

August 3, 2016

**ADMINISTRATIVE INFORMATION**

Manufacturer Name	Snyder Industries, Inc. 6940 O Street, Suite 100 Lincoln, NE 68510 Telephone: +1 (402) 467-5221 Fax: +1 (402) 465-1220
Official Contact	Herbert H. Spann Engineering Manager
Representative/Consultant	Claudia H. Fell PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: cfell@paxmed.com

**DEVICE NAME AND CLASSIFICATION**

Trade/Proprietary Name	Med-Tainer Single Deposit Container (SDC)
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

**PREDICATE DEVICE INFORMATION**

Primary predicate device:

K111085, Rehrig Pacific Company, Sharps Tank Reusable Sharps Container

**INDICATIONS FOR USE**

Med-Tainer Single Deposit Containers (SDC) are intended for the safe collection and transport of medical sharps. The reusable 10 gallon and 17 gallon containers are to be used in supervised areas of healthcare institutions such as hospitals, clinics, veterinary offices and laboratories.

<b>Med-Tainer Single Deposit Containers</b>			
<b>Med-Tainer Single Deposit Container (SDC) 10 Gallon</b>			
Model Number	Description	Approximate Size (inches)	
780300E74100	Med-Tainer SDC, 10 gallon, Red	18 L x 13 W x 16 H	
780300E74200	Med-Tainer SDC, 10 gallon, Teal	18 L x 13 W x 16 H	
780300E74300	Med-Tainer SDC, 10 gallon, Yellow	18 L x 13 W x 16 H	
780300E74400	Med-Tainer SDC, 10 gallon, Blue	18 L x 13 W x 16 H	
780300E74500	Med-Tainer SDC, 10 gallon, Green	18 L x 13 W x 16 H	
<b>Med-Tainer Single Deposit Container (SDC) 17 Gallon</b>			
Model Number	Description	Approximate Size (inches)	
780310E74100	Med-Tainer SDC, 17 gallon, Red	18 L x 13 W x 25 H	
780310E74200	Med-Tainer SDC, 17 gallon, Teal	18 L x 13 W x 25 H	
780310E74300	Med-Tainer SDC, 17 gallon, Yellow	18 L x 13 W x 25 H	
780310E74400	Med-Tainer SDC, 17 gallon, Blue	18 L x 13 W x 25 H	
780310E74500	Med-Tainer SDC, 17 gallon, Green	18 L x 13 W x 25 H	
<b>Med-Tainer Single Deposit Container Lids</b>			
Model Number	Description	Approximate Size (Inches)	Aperture (inches)
34300474	Locking Transport Lid, Black	17 L x 11 W	No opening – use to seal container for transport
34300476	Large Lab Lid, Black	17 L x 11 W	5.75 x 9.75 – use only in areas that have no unsupervised patient access
34300477	Small Lab Lid, Black	13 L x 9 W	No opening – use to cover large lab lid when not in use
78033300E74101	Restrictive Lid, Red	18.75 L x 13.5 W x 11.6 H	3.8 H x 13.8 W
78033300E74201	Restrictive Lid, Teal	18.75 L x 13.5 W x 11.6 H	3.8 H x 13.8 W
78033300E74301	Restrictive Lid, Yellow	18.75 L x 13.5 W x 11.6 H	3.8 H x 13.8 W
78033300E74401	Restrictive Lid, Blue	18.75 L x 13.5 W x 11.6 H	3.8 H x 13.8 W
78033300E74501	Restrictive Lid, Green	18.75 L x 13.5 W x 11.6 H	3.8 H x 13.8 W

**DEVICE DESCRIPTION**

Med-Tainer Single Deposit Container (SDC) is used to collect medical sharps in supervised areas of healthcare facilities. The containers are rotationally molded and made of low density polyethylene. They are available in 17 gallon and 10 gallon sizes and in five colors: red, teal, yellow, blue and green. Med-Tainer SDC is a reusable container intended to be reprocessed up to 780 times. The products are supplied to waste management companies that are responsible for transporting, decanting, decontaminating, and destroying the containers. The accompanying lids vary by purpose. The black transport lid is used during transport of the filled container. The combination of black large lab lid, with an opening to discard sharps, and the black small lab lid, used to slide across the large lab lid when not in use, allows easy disposal of sharps. The color coordinating restrictive lid with a mail box type opening is intended to prevent hand or finger access.

## PERFORMANCE DATA

### Life Span Processing Simulation per CAN/CSA Z316.6-14 BA.8.3.1 *Sharps injury protection – Requirements and test methods – Sharps containers*

Containers were processed 780 times to simulate their intended life cycle: filled with sharps, closed for transport, opened, decanted, rinsed and decontaminated. Results: all containers successfully completed 780 processing simulation cycles without damage.

### Life Span Transport Simulation per CAN/CSA Z316.6-14 BA.8.3.2 *Sharps injury protection – Requirements and test methods – Sharps containers*

Containers processed 780 times were filled with sharps and vibrated to simulate transportation. Results: all containers completed transportation simulation without damage.

### Leak Resistance Test per Health Devices, August – September 1993, ECRI, Vol 22 Nos. 8-9 pgs. 383-384

Containers processed 780 times were filled with water and checked after 24 hours for loss of fluid. Results: passed.

### Container Stability Test per ISO 23907 *Sharps injury protection – Requirements and test methods – Sharps containers*

Containers processed 780 times were filled with a material of density  $0.20 \pm 0.01\text{kg/l}$  and placed on an incline with a minimum angle of  $15^\circ$ . Testing was repeated for each side of the container. The container failed the criteria if it toppled over. Results: passed.

### Strength of Handles per ISO 23907 *Sharps injury protection – Requirements and test methods – Sharps containers*

Containers processed 780 times were filled with a mass equivalent to 150% of the manufacturer's maximum gross mass, closed, suspended by the handles for an hour at  $23 \pm 5^\circ\text{C}$  and examined for breakage or detachment. Results: passed.

### Resistance to Damage and Leakage after Dropping per ISO 23907 *Sharps injury protection – Requirements and test methods – Sharps containers*

Containers processed 780 times were conditioned for testing, filled with liquid and sharps, closed, and dropped a distance of 1 meter. The containers were oriented to land on the bottom, side wall and adjacent side wall. After landing they were inspected for leakage and /or loss of integrity. Results: passed.

### Resistance to Damage and Leakage after Dropping per ISO 23907 *Sharps injury protection – Requirements and test methods – Sharps containers (modified)*

Containers were conditioned for testing, filled with liquid, sharps, glass, and stainless steel. The fill weight of the container was 40.1 lbs. The containers were closed, and dropped a distance of 1 meter. The containers were oriented to land on the bottom, side wall and adjacent side wall. After landing they were inspected for leakage and /or loss of integrity. Results: passed.

Puncture Resistance per ASTM F2132-01 Standard Specification of Materials Used in Containers for Discarded Medical Needles and Other Sharps

Each side of the container (bottom, and 4 sides) was overlaid with a 1" x 1" grid. The 12 thinnest areas were tested using a 21 gauge by 1 inch hypodermic needle to measure the force required to penetrate the sample. The criteria to pass the puncture resistance test are an average value not less than 3.4 lbf (15 N) with no value less than 2.8 lbf (12.5 N). Results: passed.

Puncture Resistance per ASTM F2132-01 Standard Specification of Materials Used in Containers for Discarded Medical Needles and Other Sharps

Each side of the container processed 780 times (lid, bottom, and 4 sides) was overlaid with a 1" x 1" grid. The 12 thinnest areas were tested using a 21 gauge by 1 inch hypodermic needle to measure the force required to penetrate the sample. The criteria to pass the puncture resistance test are an average value not less than 3.4 lbf (15 N) with no value less than 2.8 lbf (12.5 N). Results: passed.

Drop Test per 49 CFR 178.603 Specification for Packagings – Subpart M – Testing of Non-Bulk Packagings and Packages

Containers were filled, closed, conditioned, and oriented to land during multiple trials on its top, bottom, end, side and top corner. The containers were dropped 1.2 meters, and examined for loss of contents. Results: passed.

Stack Test per 49 CFR 178.606 Specification for Packagings – Subpart M – Testing of Non-Bulk Packagings and Packages

Containers were subjected to a temperature of 104°F for 28 days with weights of 130 pounds stacked on top of them. The containers were examined for deformation or release of contents. Results: passed.

Vibration Testing per 49 CFR 178.608 Specification for Packagings – Subpart M – Testing of Non-Bulk Packagings and Packages

Containers were placed on a vertical linear vibration table operated at an amplitude of 1 inch and a frequency of 4.25 Hz for 60 minutes, and inspected for deterioration or loss of contents. Results: passed.

Cleaning Validation per FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

A cleaning validation protocol was designed and performed. All containers successfully met or surpassed performance criteria.

**EQUIVALENCE TO MARKETED DEVICE**

Snyder Industries, Inc. submits the following information in this Premarket Notification to demonstrate, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate device:

K111085, Rehrig Pacific Company, Sharps Tank Reusable Sharps Container

	Subject Device	Primary Predicate Device
Comparison	Snyder Industries, Inc. Med-Tainer Single Deposit Container	Rehrig Pacific Company Sharps Tank Reusable Sharps Container K111085
Indications for Use	Med-Tainer Single Deposit Containers are intended for the safe collection and transport of medical sharps. The reusable 10 gallon and 17 gallon containers are to be used in supervised areas of healthcare institutions such as hospitals, clinics, veterinary offices and laboratories. The Med-Tainer Single Deposit Container is available in Kelly green, Ascent blue, teal, red and yellow.	Rehrig Healthcare Systems reusable 17 gallon sharps container is intended to be used for the collection and transportation of used medical sharps. The container is intended to be used in hospitals and clinics, operating rooms, and laboratories by technicians, doctors, dentists, and veterinarians. The device is only intended for use in areas with no unsupervised patient access. Empty Weight: 9.4 lbs Color: Red with contrasting Biohazard Symbol Dimensions: 20.00"L x 12.50"W x 25.8"H Opening Dimensions: Main lid opening (approximate) - 18.00" x 10.7" Sub-lid opening (approximate) - 8.0" x 6.0" Both the main lid and sub-lid have temporary and final closures. Temporary closures are intended to allow opening and closing of the container by the user and to protect against spillage if toppled. The final closure is designed to secure the container during transport.

	Subject Device	Primary Predicate Device
Manufacturing	Rotationally molded	Injection Molded
Material	Linear Low density polyethylene	High density polyethylene
Approximate Size (inches)	18 L x 13 W x 16 H (10 gallon) 18 L x 13 W x 25 H (17 gallon)	20 L x 12.5 W x 16 H (10 gallon) 20 L x 12.5 W x 26 H (17 gallon)
Opening dimensions (length x width, inches)	Large Lab Lid opening: 5.75 x 9.75 Restrictive Lid opening: 13.7 x 4.2	Main lid opening: 18.00 x 10.7 Sub-lid opening: 8.0 x 6.0
Thickness (inches)	0.1	unavailable
Tare Weight (pounds)	10 gallon with lid: 5.5, 17 gallon with lid: 7	10 gallon: unavailable, 17 gallon: 9.4
Color	Red, Teal, Yellow, Blue Green with embossed and inked fill line; contrasting label includes Biohazard symbol	Red with contrasting Biohazard Symbol

**CONCLUSION**

The subject device is substantially equivalent to the predicate device.