

Section 5 - 510(k) Summary

1. Submission Sponsor

GRP and Associates
P.O. Box 94
218 10th Avenue N.
Clear Lake,
Iowa, 50428
USA
Phone: (800) 207 0976
Fax: (641) 357 4063
Contact: Scott Rollefson, Manager of Operations

2. Submission Correspondent

Emergo Group
816 Congress Ave.,
Suite 1400,
Austin, TX 78701
Cell Phone: 940 390 0961
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Robert Seiple, RAC, Senior Consultant, QA/RA
Email: project.management@emergogroup.com

3. Date Prepared

27 March 2014

4. Device Identification

Trade/Proprietary Name: GRP Sharps Container, models 1.5Qt, 1G, 2G and 3G
Common/Usual Name: Sharps Container
Classification Name: hypodermic single lumen needle
Classification Regulation: 21CFR 880.5570
Product Code: MMK
Device Class: Class II
Classification Panel: General Hospital

5. Predicate Devices

K112774 – BD RecyKleen Sharps Collector

6. Device Description

The GRP Sharps Container is a blow molded HDPE bottle with a spun-weld iris at the opening. The iris acts as an aperture, allowing a vertical sharps drop. The device has a yellow safety ring which prevents the cap from locking closed during use. The device has a white 2.5" cap which contains a sealing gasket. Once the GRP Sharps Container is full, the safety ring is removed prior to placing the cap on. When the safety ring has been removed, the cap locks down for a tight seal. The device is available in four sizes: 1.5 quart, 1 gallon, 2 gallon and 3 gallon. The containers are identical except for capacity.

7. Intended Use

There are four indications for use statements corresponding to the four sizes of container. These are reproduced below:

Indications for Use Statement: GRP-1.5 Qt

The empty device, as it sits, is a red container that measures 4"X4"X7.5" and weighs 6oz. The opening/closure measures 2.5" in diameter. The intended use of the vertical entry, single use, sharps containers, is to provide a receptacle for used, contaminated medical sharps, and for enclosure during transport to ultimate disposal. The container is intended to be used in hospitals, 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.

Indications for Use Statement: GRP-1G

The empty device, as it sits, is a red container that measures 9.75"X6"X9.75" and weighs 16oz. The opening/closure measures 2.5" in diameter. The intended use of the vertical entry, single use, sharps containers, is to provide a receptacle for used, contaminated medical sharps, and for enclosure during transport to ultimate disposal. The container is intended to be used in hospitals, 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.

Indications for Use Statement: GRP-2G

The empty device, as it sits, is a red container that measures 9.75"X6"X13.75" and weighs 1lb 9oz. The opening/closure measures 2.5" in diameter. The intended use of the vertical entry, single use, sharps containers, is to provide a receptacle for used, contaminated medical sharps, and for enclosure during transport to ultimate disposal. The container is intended to be used in hospitals, 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.

Indication for Use Statement: GRP-3G

The empty device, as it sits, is a red container that measures 9.75"X6"X18.75" and weighs 2lbs. The opening/closure measures 2.5" in diameter. The intended use of the vertical entry, single use, sharps containers, is to provide a receptacle for used, contaminated medical sharps, and for enclosure during transport to ultimate disposal. The container is intended to be used in hospitals, 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.

8. Comparison of Technological Characteristics

The following table compares the GRP Sharps container to the BD Medical Systems sharps container with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	GRP Associates	BD Medical Surgical Systems
Trade Name	Container, Sharps	BD Recykleen Sharps Collector
510(k) Number	TBD	K112774
Product Code	MMK	MMK
Regulation Number	21CFR 880.5570	21CFR 880.570
Regulation Name	Accessory to hypodermic single lumen needles	Accessory to hypodermic single lumen needles
Indications for Use	The empty device, as it sits, is a red container that measures (x" by y" by z") four sizes) and weighs xlbs. The opening/closure measures 2.5" in diameter. The intended use of the vertical entry, single use, sharps containers, is to provide a receptacle for used, contaminated medical sharps, and for enclosure during transport to ultimate disposal. The container is intended to be used in hospitals, 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.	Sharps Collects are intended to be used for disposal of contaminated medical sharps in health care facilities
Product classification	Class II	Class II
Requirements from FDA Guidance on Sharps Containers (Oct. 1993):		

Manufacturer	GRP Associates	BD Medical Surgical Systems
Trade Name	Container, Sharps	BD Recykleen Sharps Collector
Labeling: Biohazard labels visible on device	Yes	Yes
Disposal procedures including in labeling	Yes	Yes
Assembly, mounting procedures	None. Free standing on wide base	Free standing. Accessories available to bolt to wall.
Operating Instructions	Yes – IFU	Yes - IFU
Device Description: Volume:	1.5 Qt, 1 gallon, 2 gallon, and 3 gallon sharps containers	8 quart and 26 gallon sharps containers
Materials of Construction	Blow molded HDPE	Polyolefinic resins, virgin polypropylene
Color	Red, opaque	Red, opaque
Puncture Resistance	Complies with ASTM 2132-01 (2008) "Puncture Resistance of Materials used in containers for discarded medical needles and other Sharps".	Complies with ASTM 2132-01 (2008) "Puncture Resistance of Materials used in containers for discarded medical needles and other Sharps".
Closure	Spun-weld iris, functions as an aperture allowing vertical drop of sharps.	Flexible aperture with lockable lid
Leakproof on sides and bottom	Conforms to CSA Z316.6-95 Leak Resistance	Conforms to BS7320:1990 Leakage test
Labeled or color-coded	Labeled and color coded, biohazard labeled. See picture above	Same – biohazard labeled
Single use or reusable	Single use	Single use
Intended Location	The container is intended to be used in nursing homes, doctor's offices, dental offices, emergency room, emergency vehicles and labs for the safe disposal of hazardous sharps.	Intended for use in health care facilities
Includes features to bend, break or shear needles	No	No
Container full indication	Yes – clearly marked fill line	Yes – clearly marked fill line
Performance Standards:		
Container stability	Conforms to CZA Z316.6-07 Topple resistance	Not available
Needle Penetration Resistance	Complies with ASTM F 2132-01	Same
Leakage	Complies with CSA CZ316.5-95 and OSHA 29CFR 1910.1030	Same

The performance testing summary demonstrates substantial equivalence between the subject and predicate devices. The GRP Sharps Containers have been tested by appropriate methods with respect to relevant FDA guidance documents, FDA recognized ASTM standard F2132-01, ISO 23907, OSHA regulations 29 CFR Part 1910:1030. No new issues of safety or effectiveness were raised from the testing performed and the GRP Sharps Containers are considered substantial equivalent to the predicate device.

9. Non-Clinical Performance Data

Performance testing demonstrates compliance with the recognized consensus standard, ASTM F 2132-01, reapproved 2008, e1, "Standard Specification for Puncture Resistance of Materials used in Collectors for Discarded Medical Needles and other Sharps". In addition, the FDA Guidance Document "Guidance on the Content and Format of Premarket Notification (510(k)) submissions for Sharps, dated October 1993, was used to help identify applicable physical and mechanical features of the subject device.

Testing was conducted in accordance with:

- ASTM F 2132-01 (reapproved 2008)e. *Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps.*
- BSI 7320:1994.4 – Impact Resistance
- ISO 23907 First edition 2012-09-01 Sharps injury protection - Requirements and test methods - Sharps containers
- CSA Z316.6-95, 3.9.2.1 – Evaluation of single-use and reusable medical sharps containers for biohazardous and cytotoxic waste - Leak Resistance
- CSA Z316.6-07 - Evaluation of single-use and reusable medical sharps containers for biohazardous and cytotoxic waste -Container Stability
- CSA Z316.6-07 – Evaluation of single-use and reusable medical sharps containers for biohazardous and cytotoxic waste - Handle Strength and Fill Capacity
- CSA Z316.6-07 – Evaluation of single-use and reusable medical sharps containers for biohazardous and cytotoxic waste -Fill Capacity

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device nor is clinical testing applicable to sharps containers.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device.

We have demonstrated in this 510(k) submission that the difference between the GRP

Sharps Containers and the BD Sharps Collectors do not raise any questions regarding safety or effectiveness. Performance testing and compliance with voluntary standards, demonstrate that the GRP Sharps Containers are substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, performance characteristics, and intended use. The GRP Sharps Containers, as designed and manufactured, are determined to be substantially equivalent to the referenced predicate devices.



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

May 2, 2014

GRP and Associates
c/o Mr. Robert Seiple, RAC
Senior Consultant
Emergo Group
Suite 1400
816 Congress Avenue
Austin, TX 78701

Re: K132476

Trade/Device Name: GRP Sharps Container, models 1.5Qt, 1G, 2G, and 3G
Regulation Number: 21 CFR 880.5570
Regulation Name: Sharps Container
Regulatory Class: II
Product Code: MMK
Dated: March 18, 2014
Received: March 19, 2014

Dear Mr. Seiple:

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" (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 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,

Tejinder Parolia-Shera, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH

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 (if known)
K132476

Device Name
GRP Sharps Container

Indications for Use (Describe)

GRP Sharps Container: GRP 1.5QT: (1.5 qt capacity)

The empty device, as it sits, is a red container that measures 4"X4"X7.5" and weighs 6oz. The opening/closure measures 2.5" in diameter. The intended use of the vertical entry, single use, sharps containers, is to provide a receptacle for used, contaminated medical sharps, and for enclosure during transport to ultimate disposal. The container is intended to be used in hospitals, 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.

GRP Sharps Container GRP 1G:

The empty device, as it sits, is a red container that measures 9.75"X6"X9.75" and weighs 16oz. The opening/closure measures 2.5" in diameter. The intended use of the vertical entry, single use, sharps containers, is to provide a receptacle for used, contaminated medical sharps, and for enclosure during transport to ultimate disposal. The container is intended to be used in hospitals, 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.

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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)

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

Elizabeth F. Claverie -S
2014.05.01 22:40:41 -04'00'

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Paperwork Reduction Act (PRA) Staff
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Indications for Use

510(k) Number (if known)
K132476

Device Name
GRP Sharps Container

Indications for Use (Describe)

GRP Sharps Container GRP 2G:

The empty device, as it sits, is a red container that measures 9.75"X6"X13.75" and weighs 1lb 9oz. The opening/closure measures 2.5" in diameter. The intended use of the vertical entry, single use, sharps containers, is to provide a receptacle for used, contaminated medical sharps, and for enclosure during transport to ultimate disposal. The container is intended to be used in hospitals, 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.

GRP Sharps Container GRP 3G:

The empty device, as it sits, is a red container that measures 9.75"X6"X18.75" and weighs 2lbs. The opening/closure measures 2.5" in diameter. The intended use of the vertical entry, single use, sharps containers, is to provide a receptacle for used, contaminated medical sharps, and for enclosure during transport to ultimate disposal. The container is intended to be used in hospitals, 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.

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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)

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