



November 12, 2020

Zhejiang Gongdong Medical Technology Co., Ltd
% Ivy Wang
Technical Manager
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1309, Dongfang Building, 1500# Central Ave.
Shanghai, Shanghai 200122
China

Re: K201523

Trade/Device Name: Sharps container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: October 16, 2020
Received: October 16, 2020

Dear Ivy Wang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray, III, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K201523

Device Name
Sharps Container

Indications for Use (Describe)

Sharps Containers are intended to provide a receptacle for used, contaminated medical sharps and act as an enclosure during transport to ultimate disposal.

The Containers are single-use, disposable, non-sterile containers intended to be used for health-care purposes for safe disposal of hazardous sharps such as needles, syringes, lancets and etc. The target population is for qualified personnel in health care facilities and other facilities in which medical sharps may be used.

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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Model No.	Capacity (full line)	capacity (total)	Weight	Dimension (mm)	Thickness (mm)	Requirements for mounting	Acceptable sites of use	Description and Dimension of disposal aperture(cm)
GDC-03-F	2143ml	2972ml	224.80g	188.4*158.1*193.2	1.4	Free standing	The target population is for qualified personnel in health care facilities and other facilities in which medical sharps may be used. All the containers are intended to be used in areas where there is no unsupervised patient access.	8.2*5.2
GDC-03-X	2143ml	2972ml	234.15g	183.4*153.3*189.3	1.4	Free standing		16 sq.
GDC-05-F	4049ml	5234ml	320.50g	226.3*199.0*218.5	1.5	Free standing		9.5*5.5
GDC-05-X	4049ml		322.76g	221.0*195.9*217.5	1.5	Free standing		21sq.
GDC-07-F	5288ml	6875ml	435.28g	241.4*220.9*231.7	1.7	Free standing		9.5*5.5
GDC-07-X	5288ml	6875ml	425.32g	240.6*218.8*230.0	1.7	Free standing		21sq.
GDC-013-X	10038ml	13253ml	628.54g	281.8*252.5*307.8	1.8	Free standing		32sq.
SC-01Q	670ml	763ml	77.53g	108.2*88.4*173.7	1.05	Free standing		5*3.7

SC-02Q	910ml	1063ml	77.85g	108.6*88.3*222.8	1.2	Free standing	5*3.7
SC-05Q	4367ml	5111ml	513.61g	270.3*116.1*289.5	1.3	Free standing Locking wall bracket	22*4.5
SC-01G	2623ml	3863	220.72g	257.3*174.5*155.2	1.15	Free standing	14*5.5
SC-02G	6066ml	7424ml	489.21g	257.3*175.0*259.5	1.15	Free standing Locking wall bracket	14*6
SC-06G	14013ml	21024ml	801.56g	377.0*235.9*415.2	1.5	Free standing	21*4.5

Model No.	Material description	Color	lid configurations	Lock Method	Unwinding feature
GDC-03-F	Cap: PP; Body: Copolymerization PP	Cap: Semitransparent; Body: Yellow	Folding cap	Buckle on fold over cover and fasten cover	Located in the lid and above the containment area. The unwinder has a round entry port for the needle to pass through, allowing it to be fully enclosed within the container. The models GDC-03-F, GDC-03-X, DC-05-F, GDC-05-X, GDC-07-F, GDC-07-X, GDC-13--X SC-01Q, SC-06G, SC-02Q have the needle unwinding
GDC-03-X	Cap, small cover, handle: PP; Body: Copolymerization PP	Cap: Semitransparent; Small cover and handle: Red; Body: Yellow	Revolving cap	There is a protruding small cylinder on the reverse side of the small red cover that can rotate, and there is a small round hole on the cover. When the small cylinder rotates to the position of the small round hole, the two kinds of small cylinders cooperate and buckle each other.	

GDC-05-F	Cap: PP; Body: Copolymerization PP	Cap: Semitransparent; Body: Yellow	Folding cap	Buckle on fold over cover and fasten cover
GDC-05-X	Cap, K7:K9small cover, handle: PP; Body: Copolymerization PP	Cap: Semitransparent; Small cover and handle: Red; Body: Yellow	Revolving cap	There is a protruding small cylinder on the reverse side of the small red cover that can rotate, and there is a small round hole on the cover. When the small cylinder rotates to the position of the small round hole, the two kinds of small cylinders cooperate and buckle each other.
GDC-07-F	Cap: PP; Body: Copolymerization PP	Cap: Semitransparent; Body: Yellow	Folding cap	Buckle on fold over cover and fasten cover
GDC-07-X	Cap, small cover, handle: PP; Body: Copolymerization PP	Cap: Semitransparent; Small cover and handle: Red; Body: Yellow	Revolving cap	There is a protruding small cylinder on the reverse side of the small red cover that can rotate, and there is a small round hole on the cover. When the small cylinder rotates to the position of the small round hole, the two kinds of small cylinders cooperate and buckle each other.
GDC-013-X	Cap, small cover: PP; Body: Copolymerization PP	Cap: Semitransparent; Small cover and handle: Red; Body: Yellow	Revolving cap	There is a protruding small cylinder on the reverse side of the small red cover that can rotate, and there is a small round hole on the cover. When the small cylinder rotates to the position of the small round hole, the two kinds of small cylinders cooperate and buckle each other.
SC-01Q	Cap, small cover: PP; Body: Copolymerization PP	Cap: White; Small cover and handle:	Slid cap	Slid the buckle on the small cap, fasten tight with cap
SC-02Q	Cap, small cover: PP; Body: Copolymerization PP	Semitransparent; Body: Red	Slid cap	Slid the buckle on the small cap, fasten tight with cap

features.

SC-05Q	Cap and small cover: PP; Body: Copolymerization PP; Bottom and keys: ABS	Cap: White; Small cover: Red, Body Red; Bottom and key: Grey	Revolving cap	Small cap could revolving inside and fasten tight with the buckle in the cap
SC-01G	Cap, small cover: PP; Body: Copolymerization PP	Cap: White; Small cover and handle: Semitransparent; Body: Red	Slid cap	Slid the buckle on the small cap, fasten tight with cap
SC-02G	Cap and small cover: PP; Body: Copolymerization PP; Bottom and keys: ABS	Cap: White; Small cover and handle: Semitransparent; Body: Red	Slid cap	Slid the buckle on the small cap, fasten tight with cap
SC-06G	Cap, small cover: PP; Body: Copolymerization PP	Cap: White; Small cover and handle: Semitransparent; Body: Red	Slid cap	Slid the buckle on the small cap, fasten tight with cap

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510(K) Summary

Date of Summary prepared: 2020-11-11

A. Applicant:

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B. Device:

Trade Name: Sharps Container

Common Name: container, sharps

Regulation Number: 21 CFR 880.5570

Regulation Name: Hypodermic single lumen needle

Regulatory Class: II

Product Code: MMK

Review Panel: General Hospital

C. Predicate device:

Manufacturer	Predicate Device	510(k) Number	Submitted Device
International Marketing Specialists Inc.	Tiger Sharps container	K190240	Tiger Sharps Containers

D. Indications for Use:

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Sharps Containers are intended to provide a receptacle for used, contaminated medical sharps and act as an enclosure during transport to ultimate disposal.

The Containers are single-use, disposable, non-sterile containers intended to be used for health- care purposes for safe disposal of hazardous sharps such as needles, syringes, lancets and etc. The target population is for qualified personnel in health care facilities and other facilities in which medical sharps may be used.

The following Sharps Container models and accessories are described in this submission:

Table1: specification of the sharps container

Model No.	Capacity (full line)	capacity (total)	Weight	Dimension (mm)	Thickness (mm)	Requirements for mounting	Acceptable sites of use	Description and Dimension of disposal aperture(cm)
GDC-03-F	2143ml	2972ml	224.80g	188.4*158.1*193.2	1.4	Free standing	The target population is for qualified personnel in health care facilities and other facilities in which medical sharps may be used. All the containers are intended to be used in areas where there is no unsupervised	8.2*5.2
GDC-03-X	2143ml	2972ml	234.15g	183.4*153.3*189.3	1.4	Free standing		16 sq.
GDC-05-F	4049ml	5234ml	320.50g	226.3*199.0*218.5	1.5	Free standing		9.5*5.5
GDC-05-X	4049ml		322.76g	221.0*195.9*217.5	1.5	Free standing		21sq.
GDC-07-F	5288ml	6875ml	435.28g	241.4*220.9*231.7	1.7	Free standing		9.5*5.5

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GDC-07-X	5288ml	6875ml	425.32g	240.6*218.8*230.0	1.7	Free standing	patient access.	21sq.
GDC-013-X	10038ml	13253ml	628.54g	281.8*252.5*307.8	1.8	Free standing		32sq.
SC-01Q	670ml	763ml	77.53g	108.2*88.4*173.7	1.05	Free standing		5*3.7
SC-02Q	910ml	1063ml	77.85g	108.6*88.3*222.8	1.2	Free standing		5*3.7
SC-05Q	4367ml	5111ml	513.61g	270.3*116.1*289.5	1.3	Free standing Locking wall bracket		22*4.5
SC-01G	2623ml	3863	220.72g	257.3*174.5*155.2	1.15	Free standing		14*5.5
SC-02G	6066ml	7424ml	489.21g	257.3*175.0*259.5	1.15	Free standing Locking wall bracket		14*6
SC-06G	14013ml	21024ml	801.56g	377.0*235.9*415.2	1.5	Free standing		21*4.5

Model No.	Material description	Color	lid configurations	Lock Method	Unwinding feature
GDC-03-F	Cap : PP ; Body : Copolymerization PP	Cap : Semitransparent ; Body : Yellow	Folding cap	Buckle on fold over cover and fasten cover	<p>Located in the lid and above the containment area. The unwinder has a round entry port for the needle to pass through, allowing it to be fully enclosed within the container. The models GDC-03- F, GDC-03-X, DC-05-F, GDC-05-X, GDC-07-F, GDC-07-X, GDC-13-X, SC-01Q, SC-06G, SC-02Q have the needle unwinding features.</p>
GDC-03-X	Cap, small cover, handle : PP ; Body : Copolymerization PP	Cap : Semitransparent ; Small cover and handle: Red; Body : Yellow	Revolving cap	There is a protruding small cylinder on the reverse side of the small red cover that can rotate, and there is a small round hole on the cover. When the small cylinder rotates to the position of the small round hole, the two kinds of small cylinders cooperate and buckle each other.	
GDC-05-F	Cap : PP ; Body : Copolymerization PP	Cap : Semitransparent ; Body : Yellow	Folding cap	Buckle on fold over cover and fasten cover	
GDC-05-X	Cap, K7:K9small cover, handle : PP ; Body : Copolymerization PP	Cap : Semitransparent ; Small cover and handle: Red; Body : Yellow	Revolving cap	There is a protruding small cylinder on the reverse side of the small red cover that can rotate, and there is a small round hole on the cover. When the small cylinder rotates to the position of the small round hole, the two kinds of small cylinders cooperate and buckle each other.	
GDC-07-F	Cap : PP ; Body : Copolymerization PP	Cap : Semitransparent ; Body : Yellow	Folding cap	Buckle on fold over cover and fasten cover	
GDC-07-X	Cap, small cover, handle : PP ; Body : Copolymerization PP	Cap : Semitransparent ; Small cover and handle: Red; Body : Yellow	Revolving cap	There is a protruding small cylinder on the reverse side of the small red cover that can rotate, and there is a small round hole on the cover. When the small cylinder rotates to the position of the small round hole, the two kinds of small cylinders cooperate and buckle each other.	

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GDC-013-X	Cap, small cover : PP ; Body : Copolymerization PP	Cap : Semitransparent ; Small cover and handle: Red; Body : Yellow	Revolving cap	There is a protruding small cylinder on the reverse side of the small red cover that can rotate, and there is a small round hole on the cover. When the small cylinder rotates to the position of the small round hole, the two kinds of small cylinders cooperate and buckle each other.
SC-01Q	Cap, small cover : PP ; Body : Copolymerization PP	Cap : White ; Small cover and handle:	Slid cap	Slid the buckle on the small cap, fasten tight with cap
SC-02Q	Cap, small cover: PP ; Body : Copolymerization PP	Semitransparent; Body : Red	Slid cap	Slid the buckle on the small cap, fasten tight with cap
SC-05Q	Cap and small cover : PP ; Body : Copolymerization PP ; Bottom and keys : ABS	Cap: White; Small cover: Red, Body Red; Bottom and key: Grey	Revolving cap	Small cap could revolving inside and fasten tight with the buckle in the cap
SC-01G	Cap, small cover : PP ; Body : Copolymerization PP	Cap : White ; Small cover and handle: Semitransparent; Body : Red	Slid cap	Slid the buckle on the small cap, fasten tight with cap
SC-02G	Cap and small cover : PP ; Body : Copolymerization PP ; Bottom and keys : ABS	Cap : White ; Small cover and handle: Semitransparent; Body : Red	Slid cap	Slid the buckle on the small cap, fasten tight with cap
SC-06G	Cap, small cover : PP ; Body : Copolymerization PP	Cap : White ; Small cover and handle: Semitransparent; Body : Red	Slid cap	Slid the buckle on the small cap, fasten tight with cap

E. Device Description:

Sharps container are used to collect hazardous sharps such as needles, syringes, lancets and etc. The containers are single-use, disposable, non-sterile containers.

The Sharps Container constructed of polypropylene plastic. No part of the container is intended to come in contact with patients. The containers are designed to be puncture resistant, leak resistant on the sides and bottom, impact resistant, closable, and stable.

F. Technological Characteristics

Table 2: comparison of the proposed and Predicate device

Element of Comparison	Subject Device	Predicate Device	Result
Manufacture	Zhejiang Gongdong Medical Technology Co., Ltd	International Marketing Specialists Inc.	
FDA510(K) Number	/	K190240	--
Device Name	Sharps Containers	Tiger Sharps Containers	Similar
Intended Use	Sharps Containers are intended to provide a receptacle for used, contaminated medical sharps and act as an enclosure during transport to ultimate disposal.	Tiger Sharps Containers are intended to provide a receptacle for used, contaminated medical sharps and act as an enclosure during transport to ultimate disposal.	Same
Product code	MMK	MMK	Same
Regulation Number	21CFR880.5570	21CFR880.5570	Same
Class	II	II	Same
Capacities	2972ml,2972ml,5234ml,6875ml,6875ml,13253ml,763ml,1063ml,5111ml,3863,7424ml,21024ml	1 Quart / 5 Quart / 2 Gallon / 2 Gallon B / 15 Liter 3 Gallon/ 8 Gallon	Analysis
Prescribed	OTC	OTC	Same
Weight Range (grams)	77.53-801.56g	109 - 1172	Analysis
No. of Piece	2-3	2-3	Similar
Material	Polypropylene, Copolymerization polypropylene	Polypropylene	Similar
Non-sterile	Yes	Yes	Same

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Method of Manufacture	Injection Molded	Injection Molded	Same
Performance testing (puncture, impact, drop, stability, integrity etc.)	Pass	Pass	Same
Disposable or Reusable?	Disposable	Disposable	Same

Difference analysis:

The design and manufacture process of the Sharps Containers is similar to the predicate chosen. There are minor differences between the devices including Size, Capacities, Weight Range.

G. Non-Clinical Performance Testing:

Performance testing was performed to validate and verify that the Sharps Container met all the requirements of related international standards and product specifications. Results of these tests demonstrate the device meets the acceptance criteria of these standards.

Table 3: Non-Clinical Performance Testing

NO.	Test	Test method	Purpose	Acceptance Criteria	Results
1	Anti-penetrability	ASTM F2132-01(Reapproved 2008e1)	Prevent the sharps in the container from penetrating the side and bottom of the container and hurting the user.	The puncture resistance of each section of the container greater than 15 N and the puncture resistance performance should met.	Pass
2	Resistance to damage and leakage after dropping	ISO 23907	Prevent the container from breaking when falling from a height, and the sharps leak from the container.	Containers remained upside down for 60 minutes while being observed for leakage. No leakage observed and there is also no liquid leakage	Pass
3	Stack Test	49 CFR 178.606	The container will not be damaged during storage and shipping while stacking.	The minimum height of the stack, including the test sample, is 3 meters. Upon completion of the stack test, containers observed for deformation. The containers should not be deteriorated.	Pass

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4	Vibration Test	49 CFR 178.608	Packaging cartons and products will not be damaged due to product transportation vibration	The containers should not be deteriorated.	Pass
5	Stability	ISO 23907	Prevent the product from dumping during use.	The container should not slide or topple.	Pass
6	Strength of handles	ISO 23907	Prevent the handle from breaking or separating during use	The containers remained intact and handles should not rupture, tear, crack, or separate from the container.	Pass

Clinical Testing: Not Applicable.

H. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K190240).