December 22, 2025

Zhejiang Gongdong Medical Technology Co., Ltd
Jingxiang Zhang
Quality Director
No 10 & 39, Beiyuan Ave.
No. 88 Jingxian Rd Huangyan
Taizhou, Zhejiang 318020
China

Re: K253222
Trade/Device Name: Gongdong Sharps Container (SCR-01Q, SCR-01G, SCR-03G)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: September 28, 2025
Received: September 29, 2025

Dear Jingxiang Zhang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

STEPHEN A. ANISKO -S
Digitally signed by STEPHEN A. ANISKO -S
Date: 2025.12.22 15:54:07 -05'00'

Stephen Anisko
Acting Assistant Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253222

Device Name
Gongdong Sharps Container (SCR-01Q. SCR-01G, SCR-03G)

Indications for Use *(Describe)*
Gongdong sharps Containers (SCR-01Q, SCR-01G, SCR-03G) 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. All device models are not in contact with or available to the patient in normal use, and all device models are not for use in areas with unsupervised patient access.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

The assigned 510(k) number is: K253222
Prepared By Date: December 22, 2025

A: Applicant:

Company:	Zhejiang Gongdong Medical Technology Co., Ltd
Address:	A) No 10 & 39 ,Beiyuan Ave. B) No.88 Jingxian Rd. Huangyan TAIZHOU Zhejiang, CN 318020
Company Contact Person:	Jingxiang Zhang
Position:	Quality Director
Phone:	86-576-84081126
Email:	RA@gongdong.com
Establishment Registration:	3005739529

B. Device:

Device Common Name:	Sharps Container
Device Trade/Proprietary Name:	Gongdong Sharps Container (SCR-01Q, SCR-01G, SCR-03G)
Classification Regulation:	21 CFR 880.5570
Classification Name:	Hypodermic Single Lumen Needle
Device Classification:	Class II
Device Product Code:	MMK
Review Panel:	General Hospital

C. Predicate Device:

Manufacturer	Device Name	Trade Name	510(k) Number
Ningbo Maxcon Medical Technology Co., Ltd	Sharps Container	Maxcon Sharps Container (MA1112)	K222905
Ningbo Maxcon Medical Technology Co., Ltd	Sharps Container	Maxcon Sharps Container (MA1221)	K180984

D. Indications for Use:

Gongdong sharps Containers (SCR-01Q, SCR-01G, SCR-03G) 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. All device models are not in contact with or available to the patient in normal use, and all device models are not for use in areas with unsupervised patient access.

Table 1: Specification of Sharps Container

Item#	Dimensions of the device model(L x W x H) mm	Colors available for the model	Materials	Description and dimensions of the sharps disposal aperture(s) mm	Special			Requirements for mounting	Weight (empty) gram	Allowable gross weight in Kg	Capacity (total)	Capacity (full line)	Acceptable sites of use (patient access)
					Locking mechanism	Needle unwinders	Recapper						
SCR-01Q	108*101*154	Red barrel, translucent lid	Lid: Polypropylene Barrel: Polypropylene	Opening 1: 41*31 Opening 2: ϕ19	Hinged closure	yes	yes	Holder with Double face adhesive tape, Free standing	lid：24±5 barrel：82±8	0.87kg	1 QUART	0.581 QUART	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.
SCR-01G	254*176*122	Red barrel, translucent lid	Lid: Polypropylene Barrel: Polypropylene	204*29.5	folding door	no	no	Locking wall bracket	lid：92±8 barrel：167±10	3.8kg	1 GAL	0.77 GAL	
SCR-03G	336*151*341	Red barrel, translucent lid	Lid: Polypropylene Barrel: Polypropylene	204*29.5	folding door	no	no	Locking wall bracket	lid：105±8 barrel：455±10	11.9kg	3 GAL	2.06 GAL	

E. Device Description:

Gongdong sharps container (SCR-01Q, SCR-01G, SCR-03G) 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

Characteristic	Submitted Subject Device	Predicate Device	Second Predicate Device	Comparison
510(k)		K222905	K180984	N/A
Device Name	Gongdong Sharps Container (SCR-01Q. SCR-01G, SCR-03G)	Maxcon Sharps container	Maxcon Sharps Container	N/A
Product code	MMK	MMK	MMK	Same
Regulation No.	21 CFR 880.5570	21 CFR 880.5570	21 CFR 880.5570	Same
Class	II	II	II	same
Indications for Use	Gongdong sharps containers (SCR-01Q, SCR-01G, SCR-03G) 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. All device models are not in contact with or available to the patient in normal use, and all device models are not for use in areas with unsupervised patient access.	Maxcon Sharps containers (1 QT Sharps Container, MA1112 ） are single-use, disposable, non-sterile containers, intended to provide a receptacle for used, contaminated medical sharps and act as an enclosure during transport to ultimate disposal. The device is intended to be used for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets, and blood needles by qualified personnel in health care facilities and other facilities in which medical sharps may be used. All device models are not in contact with or available to the patient in normal use, and all device models are not for use in areas with unsupervised patient access.	Maxcon Sharps containers (2 G Sharp Container MA1221) are single-use, disposable, non-sterile containers intended to be used for health-care purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets and blood needles. 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.	same
Size	1 Quart (SCR-01Q) 1 Gallon (SCR-01G) 3 Gallon (SCR-03G)	1 Quart (MA1112)	2 Gallon (MA1221)	similar
Dimensions (mm)	108*101*154 (SCR-01Q) 254*176*122 (SCR-01G)	101.82*108.31*154(MA1112)	316x152x230 (MA1221)	different
(L x W x H)	336*151*341 (SCR-03G)			

Single or re-usable use	Single use/disposable	Single use/disposable	Single use/disposable	Same
Weight	106g (SCR-01Q) 259g (SCR-01G) 560g (SCR-03G)	90.6g (MA1112)	421g (MA1221)	Different
No. of Pieces	2	2	2	Same
Sterile or not	Non-sterile	Non-sterile	Non-sterile	Same
Material	Poly-propylene (P.P)	Poly-propylene (P.P)	Poly-propylene (P.P)	same
Body Color	Red base, Translucent lid	Red base, Translucent lid	Red base, Translucent lid	Same
Clarity	Opaque/translucent	Opaque/translucent	Opaque/translucent	Same
Method of Manufacture	Injection Molded	Injection Molded	Injection Molded	Same
Performance testing (puncture, impact, drop, stability, integrity)	Pass	Pass	Pass	Same
Standards	ISO23907-1:2019	ISO23907-1:2019	ASTM F2132 -01(2008) ISO23907:2012	Same
Lid configurations	Opening hinge (SCR-01Q) Folding door (SCR-01G) Folding door (SCR-03G)	Opening hinge (MA1112)	Folding door (MA1221)	Same
Accessories	Holder with Double face Adhesive tape, Free standing (SCR-01Q) Locking wall bracket (SCR-01G) Locking wall bracket (SCR-03G)	Holder (made of P.P) with Double face adhesive tape is available for use with 1 quart container (MA1112) in locking on desk top by double face adhesive tape.	Free standing or bracket	similar

Summary of technological characteristics

Gongdong sharps containers (SCR-01Q, SCR-01G, SCR-03G) have the following indications for use and technological characteristics as compared to the predicate device.:
1) The same indication for use, and targeted population, and similar site of use
2) The same product structure, disposable and non-sterile sharps containers.
3) The same method of manufacture: injection molded of polypropylene.
4) The same lid configuration: Opening hinge, folding door.
All containers can be successfully passed through the same test items (i.e. Container Stability, Strength of Handle, Resistance to penetration and Resistance to Damage and leakage after dropping and Resistance to Damage and leakage after toppling as described in ISO23907-1:2019). Although the subject device and predicate device are similar on container size & accessories; are differ on dimensions & weight, the differences in technological characteristics do not impair the subject devices from their intended functions of disposal and storage of sharp waste.

G. Non-Clinical Performance Testing:

Performance testing were performed to validate and verify that Gongdong 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 Item	Test Standards Referred	Testing Purpose	Acceptance Criteria	Test Results
1	Container Stability	ISO23907-1:2019	Prevent the product from dumping during use.	The container shall not topple over when tested	Passed
2	Strength of Handles	ISO23907-1:2019	Prevent the handle from breaking or separating during use.	The handle/carrying feature shall not break or detach during testing	Passed
3	Resistance To penetration	ISO23907-1:2019	Prevent the sharps in the container from penetrating the side and bottom of the container and hurting the user.	The force needed to penetrate test specimens of the container shall be a minimum of 16N and an average of 18N or greater	Passed
4	Resistance To damage And leakage After dropping	ISO23907-1:2019	Prevent the container from breaking when falling from a height, and the sharps leak from the container.	There shall be no evidence of leakage and no breach of the sharps containment area after tested	Passed
5	Resistance To damage And leakage After toppling	ISO23907-1:2019	Prevent the container from breaking when toppling, and the sharps leak from the container.	There shall be no evidence of leakage and no breach of the sharps containment area after tested	Passed

6	Stacking Test	49CFR 178.606	The container will not be damaged during storage and shipping while stacking.	No test sample may leak. No test sample may show any deterioration which could adversely affect transportation safety or any distortion likely to reduce its strength, cause instability in stacks of packages, or cause damage to inner packaging likely to reduce safety in transportation.	Passed
7	Vibration Test	49CFR 178.608	Packaging cartons and products will not be damaged due to product transportation vibration	There is no rupture or leakage from any of the packages. No test sample should show any deterioration which could adversely affect transportation safety or any distortion liable to reduce packaging strength.	Passed
8	Sharps access and closure for repeated openings and closings	Manufacturer's internal testing SOP	Ensure the access and closure at lid are functioning well during use.	After the simulated time of Sharps access and closure for repeated openings and closings of the Sharps containers, all locking mechanism of the samples should be of no malfunction, and should lock sharps container permanently and securely	Passed
9	Usable Capacity Test	Manufacturer's internal testing SOP	Ensure the container loading volumes are within designed specs.	The difference between the measured capacity volume and designed capacity should be within ±3%.	Passed
10	Leak Proof on the sides and bottom	OSHA Regulations (Standards - 29 CFR) Bloodborne Pathogens. 1910.1030, (d)(2)(viii)(C)	Ensure the barrel integrity.	leak proof on the sides and bottom	Passed

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 (K222905 & K180984).