May 22, 2026

Taizhou Huangyan Guanhong Plastic Steel Products Factory
Chenghao Lu
General Manager
Chengjiang St. Industrial Park, Huangyan District
Taizhou, Zhejiang 318020
China

Re: K253773
Trade/Device Name: Guanhong Sharps Container (GHW-1F1); Guanhong Sharps Container (GHW-1F4); Guanhong Sharps Container (GH-6FA); Guanhong Sharps Container (GHW-2FR); Guanhong Sharps Container (GHW-8FR); Guanhong Sharps Container (GH-3FS); Guanhong Sharps Container (GHW-15FS); Guanhong Sharps Container (GHW-27FS); Guanhong Sharps Container (GH-5FSW); Guanhong Sharps Container (GHW-3FT); Guanhong Sharps Container (GHW-4FT); Guanhong Sharps Container (GHW-5FT); Guanhong Sharps Container (GHW-8FT); Guanhong Sharps Container (GH-9FY); Guanhong Sharps Container (GHW-3FY); Guanhong Sharps Container (GHW-5FY); Guanhong Sharps Container (GHW-2FY2); Guanhong Sharps Container (GHW-3FY2); Guanhong Sharps Container (GHW-5FY2); Guanhong Sharps Container (GH-1RA)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: April 21, 2026
Received: April 22, 2026

Dear Chenghao Lu:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.05.22 16:08:57 -04'00'

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)*
K253773

Device Name

Guanhong Sharps Container (GHW-1F1); Guanhong Sharps Container (GHW-1F4); Guanhong Sharps Container (GH-6FA); Guanhong Sharps Container (GHW-2FR); Guanhong Sharps Container (GHW-8FR); Guanhong Sharps Container (GH-3FS); Guanhong Sharps Container (GHW-15FS); Guanhong Sharps Container (GHW-27FS); Guanhong Sharps Container (GH-5FSW); Guanhong Sharps Container (GHW-3FT); Guanhong Sharps Container (GHW-4FT); Guanhong Sharps Container (GHW-5FT); Guanhong Sharps Container (GHW-8FT); Guanhong Sharps Container (GH-9FY); Guanhong Sharps Container (GHW-3FY); Guanhong Sharps Container (GHW-5FY); Guanhong Sharps Container (GHW-2FY2); Guanhong Sharps Container (GHW-3FY2); Guanhong Sharps Container (GHW-5FY2); Guanhong Sharps Container (GH-1RA)

Indications for Use (Describe)

Guanhong Sharps containers 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.

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
K253773

The assigned 510(k) number is: K253773

1. Submitted By:

Taizhou Huangyan Guanhong Plastic Steel Products Factory

Chengjiang Street Industrial Park, Huangyan District, Taizhou Zhejiang, CN 318020 Establishment Registration Number: 3030519472

2. Primary Contact:

Chenghao Lu

General Manager

Taizhou Huangyan Guanhong Plastic Steel Products

Factory Phone: 86-576-8462538

Email: quality@superg-med.com

3. Name of the Device:

Device Name: Guanhong Sharps Container

Trade Name: Guanhong Sharps Container (GHW-1F1); Guanhong Sharps Container (GHW-1F4); Guanhong Sharps Container (GH-6FA); Guanhong Sharps Container (GHW-2FR); Guanhong Sharps Container (GHW-8FR); Guanhong Sharps Container (GH-3FS); Guanhong Sharps Container (GHW-15FS); Guanhong Sharps Container (GHW-27FS); Guanhong Sharps Container (GH-5FSW); Guanhong Sharps Container (GHW-3FT); Guanhong Sharps Container (GHW-4FT); Guanhong Sharps Container (GHW-5FT); Guanhong Sharps Container (GHW-8FT); Guanhong Sharps Container (GH-9FY); Guanhong Sharps Container (GHW-3FY); Guanhong Sharps Container (GHW-5FY); Guanhong Sharps Container (GHW-2FY2); Guanhong Sharps Container (GHW-3FY2); Guanhong Sharps Container (GHW-5FY2); Guanhong Sharps Container (GH-1RA)

4. Classification Information:

Product Code: MMK

Device Class: Class II

CFR Reference: 21 CFR 880.5570

Classification: Hypodermic single lumen needle

Classification Panel: General Hospital

5. Predicate Device:

Trade name: Maxcon Sharps Container

Regulation Description: Hypodermic single lumen needle.

Product Code: MMK

Regulation Number: CFR880.5570

Device Class: II

The device 510k number is K180984, manufactured by Ningbo Maxcon Medical Technology Co., Ltd, located in No.228,Dongxin Road, Dongqiao Town, Ningbo, Zhejiang Province, China.

- **Reference Device 1:**

Trade name: Maxcon Sharps Container (1 QT Sharps Container, MA1112), Maxcon Sharps Container (5.4 QT Sharps Container, MA1212), Maxcon Sharps Container (5.4 QT Sharps Container, MA1213), Maxcon Sharps Container (7 Liter Sharps Container, MA1324) Regulation Description: Hypodermic single lumen needle.

Product Code: MMK

Regulation Number: CFR880.5570

Device Class: II

The device 510k number is K222905, manufactured by Ningbo Maxcon Medical Technology Co., Ltd, located in No.228,Dongxin Road, Dongqiao Town, Ningbo, Zhejiang province, China.

- **Reference Device 2:**

Trade name: Sharps Container

Regulation Description: Hypodermic

single lumen needle. Product Code: MMK

Regulation Number: CFR880.5570

- Device Class: II

The device 510k number is K201523, manufactured by Zhejiang Gongdong Medical Technology Co., Ltd, located in No.10, Beiyuan Avenue, Huangyan, Taizhou City, Zhejiang Province, China

6. Indications for Use:

Guanhong Sharps containers 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.

7. Device Description:

Guanhong Sharps Containers are of injection molded polypropylene plastic, and designed for a single-use by qualified personnel in health care facilities and other facilities in which medical sharps may be used. 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.

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.

Table 1: Description of Devices

#	Model#	Product dimensions after assembled (LxWxH)mm	Description and dimensions of the sharps disposal aperture	Locking mechanism	with needle unwinders?	with handle?	Requirements for mounting	Weight (empty) gram	Capacity (total)	Capacity (full line)	Barrel material	Barrel dimensions (mm)	Min. Barrel thickness (mm)	Barrle color	Lid configuration	Lid material	Lid dimensions (mm)	Min. Lid thickness (mm)	Lid Color	Acceptable sitesof use (patientaccess)
001	GHW-1F1	108.1x99.9x157.5	opening 1：43x30mm (LxW); opening 2：OD 20mm;	Hinged closure	yes	no	Free standing or holder with double face adhesive tape	85	0.9L	0.72L	PP	92.7x92.7x152	1.4	Red or Yellow	Single hinged opening	PP	108.1x99.9x16.8	1.5	Clear or White	The targetpopulation isfor qualifiedpersonnel inhealth carefacilities andOther facilitiesin whichmedicalsharps may beused. All thecontainers areintended to beused in areaswhere there isno unsupervisedpatient access.
002	GHW-1F4	127.2x113.8x136.1	opening：65*65mm (LxW)	Hinged closure	yes	no	Free standing or holder with double face adhesive tape	85	1L	0.8L	PP	110.7x110.7x130.1	1.2	Red or Yellow	Single hinged opening	PP	127.2x113.8x12.5	1.08	Clear or White	
003	GH-6FA	235.9x205.2x294.3	Elliptical opening：	Rotary door	yes	yes	Free standing or holder with double face adhesive tape	463	6.5L	5.2L	PP	235.9x205.2x241.7	1.8	Red or Yellow	Single rotating opening	PP	197.4x197.4x58.5	1.4	Red & Yellow	
004	GHW-2FR	160.3x116.3x179.1	Fan shaped opening：R45mm × 160°	Rotary door	yes	no	Free standing or holder with double face adhesive tape	179	2L	1.6L	PP	156.8x113.3x161.6	1.5	Red or Yellow	Single rotating opening	PP	160.3x116.3x20	1.7	Clear & Red	
005	GHW-8FR	396.9x276.7x440	Fan shaped opening：R45mm × 160° Large rectangle opening：228*121mm	Semi-circular opening：Rotary door Large rectangle opening：Hinged closure	yes	yes	Free standing or holder with double face adhesive tape	1095	8 Gallon	6.4 Gallon	PP	411.4x267.2x430	1.8	Red or Yellow	Rotating opening & hinged opening	PP	396.9x276.7x21.85	1.8	Clear & Red	
006	GH-3FS	201.6*158.4*130.8	Irregular Opening	Sliding door	yes	no	Free standing or holder with double face adhesive tape	125	2.5L	2L	PP	196.9x156.7x120	1	Red or Yellow	Single sliding opening	PP	201.6*158.4*16.3	1	White & Red	
007	GHW-15FS	380.5x237.1x263	Irregular Opening	Sliding door	yes	yes	Free standing or holder with double face adhesive tape	587	15L	12L	PP	380.5x237.1x253	1.4	Red or Yellow	Single sliding opening	PP	362.7x226.9x23	2	Clear & Red	
008	GHW-27FS	382.7x276.9x386.8	Rectangle opening：238x91 mm	Sliding door	yes	no	Free standing or holder with double face	939	27L	21.6L	PP	377.8x272x385.4	1.5	Red or Yellow	Single sliding opening	PP	382.7x276.9x76.23	1.3	White & Red	
009	GH-5FSW	258.7x175.1x151.9	Irregular opening：176*70 mm	Sliding door	yes	no	Free standing or holder with double face adhesive tape	205	5L	3.5L	PP	256x173.2x138.6	1.8	Red or Yellow	Single sliding opening	PP	258.7x175.1x20.8	1.5	White & Red	
010	GHW-3FT	246.6x201.1x135.1	Fan shaped opening：R45*120°	Rotary door	yes	yes	Free standing or holder with double face	176	2.5 Quart	2 Quart	PP	241.8x199.6x120.3	1.2	Red or Yellow	Single rotating opening	PP	246.6*201.1*30.6	1.6	Clear & Red	
011	GHW-4FT	197.8x131.9x211.7	Irregular opening：170*45. 3mm	Hinged closure	yes	yes	Free standing or holder with double face adhesive tape	229	4L	3.2L	PP	197.8x131.9x201.8	1.3	Red or Yellow	Single hinged opening	PP	196.7x127.8x18.9	0.85	Clear & Red	

012	GHW-5FT	246.6x201.1x168	Fan shaped opening : R44*120°	Rotary door	yes	yes	Free standing or holder with double face adhesive tape	251	5L	3.5L	PP	241.8x199.6x144.5	1	Red or Yellow	Single rotating opening	PP	246.6*201.1*30.6	1.6	Clear & Red
013	GHW-8FT	246.6x201.1x271.6	Fan shaped opening : R44*120°	Rotary door	yes	yes	Free standing or holder with double face adhesive tape	356	8L	6.4L	PP	241.8x199.6x248	1	Red or Yellow	Single rotating opening	PP	246.6*201.1*30.6	1.6	Clear & Red
014	GH-9FY	326.4x202.1x282.6	Rectangle opening: 235*48 mm	Counter balanc	Yes	yes	Locking wall bracket	472	9L	7.2L	PP	326.4x191.9x236	1.6	Red or Yellow	Counter Bal	PP	303.8x202.1x54.5	1.4	Clear or White
015	GHW-3FY	347.05x149.26x417.93	Rectangle opening: 220*64 mm	Counter balanc	No	yes	Locking wall bracket	578	3 Gallon	2.4 Gallon	PP	347.05x143.87x339	1.4	Red or Yellow	Counter Bal	PP	315.5x151.3x60.8	1.7	Clear or White
016	GHW-5FY	272x117x301.6	Rectangle opening: 217*47 mm	Counter balanc	No	no	Locking wall bracket	387	5 Quart	4 Quart	PP	261.8x115x229.5	1.35	Red or Yellow	Counter Bal	PP	272x117x52.7	1.2	Clear or White
017	GHW-2FY2	275.2x175x291.3	Rectangle opening: 194*47 mm	Counter balanc	Yes	yes	Locking wall bracket	359	2 Gallon	1.6 Gallon	PP	275.2x171x244	1.3	Red or Yellow	Counter Bal	PP	260x175x56	1.3	Clear or White
018	GHW-3FY2	378.2x182.4x338.2	Rectangle opening: 240*75.5mm	Counter balanc	Yes	yes	Locking wall bracket	622	3 Gallon	2.4 Gallon	PP	378.2x178.74x279.39	1.5	Red or Yellow	Counter Bal	PP	364.6x182.4x76.26	1.3	Clear or White
019	GHW-5FY2	309.6x115x290.6	Rectangle opening: 194*33.8mm	Counter balanc	Yes	yes	Locking wall bracket	368	5.4 Quart	4.32 Quart	PP	309.6x115x248.7	1.6	Red or Yellow	Counter Bal	PP	266x114.7x49.4	1.4	Clear or White
020	GH-1RA	Dia124.2 x H109.2	Fan shaped opening: R44.2mm × 120°	Rotary door	yes	no	Free standing or holder with double face adhesive tape	63	0.6L	0.48L	PP	Dia122 x H88.73	0.9	Red or Yellow	Single rotati	PP	Dia124.2 x H27.5	1	Red & Yellow

8. Comparing to Predicate Device:

Table 2: Comparison of Technological Characteristics

Characteristic	Submitted Subject Device	Predicate Device	Reference Device 1	Reference Device 2	Comparison
510(k)	K253773	K180984	K222905	K201523	N/A
Device Name	Guanhong Sharps Container	Maxcon Sharps Container	Maxcon Sharps container	Sharps container	N/A
Product code	MMK	MMK	MMK	MMK	Same
Regulation No.	21 CFR 880.5570	21 CFR 880.5570	21 CFR 880.5570	21 CFR 880.5570	Same
Class	II	II	II	II	Same
Indications for Use	Guanhong Sharps containers 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 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.	Maxcon Sharps containers 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.	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.	Same

Size	GHW-1F1, 0.9L ; GHW-1F4, 1 L ; GH-6FA, 6.5L ; GHW-2FR, 2L ; GHW-8FR, 8 Gallon ; GH-3FS, 2.5L; GHW-15FS, 15L; GHW-27FS, 27L; GH-5FSW, 5L; GHW-3FT, 2.5Quart; GHW-4FT, 4L; GHW-5FT, 5L; GHW-8FT, 8L; GH-9FY, 9L; GHW-3FY, 3Gallon; GHW-5FY, 5Quart; GHW-2FY2, 2Gallon; GHW-3FY2, 3Gallon; GHW-5FY2, 5.4 Quart; GH-1RA, 0.6L	MA1122, 2.2 QT ; MA1352, 8G	MA1112, 1 QT; MA1212, 5.4 QT; MA1213, 5.4 QT	GDC-03-X, 2.972L ; GDC-05-X, 5.234L; GDC-07-X, 6.875L; SC02Q, 1.063L; SC06G, 21,024l.	Different
Dimensions (mm) (L x W x H)	Various See device description	MA1122, 160x120x181mm; MA1352, 390x276x435mm	MA1112, 101.82x108.31x154mm; MA1212, 311.13x113.85x291.06mm; MA1213, 310x116.2x315.31mm	GDC-03-X, 183.4*153.3*189.3mm; GDC-05-X, 221.0*195.9*217.5mm; GDC-07-X, 240.6*218.8*230.0mm; SC02Q, 108.6*88.3*222.8mm; SC06G, 377.0*235.9*415.2mm.	Different
Single or re-usable use	Single use/disposable	Single use/disposable	Single use/disposable	Single use/disposable	Same
Weight range	63 to 1095g	175 to 1220g	90.6 to 422g	77.85 to 801.56g	Different
No. of Pieces	2 to 4	2	2 to 4	2 to 4	Same
Sterile or not	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Same
Material	Poly-propylene (P.P)	Poly-propylene (P.P)	Poly-propylene (P.P)	Polypropylene (PP), Copolymerization polypropylene	Same
Body Color	Red/yellow base	Red base,	Red base,	Red/yellow base,	Same

	Translucent/Red/White/Yellow lid	Translucent/red lid	Translucent/white lid	Translucent/red/white lid	
Clarity	Opaque/translucent	Opaque/translucent	Opaque/translucent	Opaque/translucent	Same
Performance testing (puncture, impact, drop, stability, integrity)	Pass	Pass	Pass	Pass	Same
Standards	ISO 23907-1:2019	ISO 23907-1:2019	ISO 23907-1:2019	ASTM F2132-01 (Reapproved 008e1) ISO23907	Same
Lid Configuration	Hinged, closure, rotary door, sliding door, counter balanced door	Rotary door	Hinged closure, counter balanced door	Revolving cap, Slid cap	Same
Accessories	Free standing or holder with double face adhesive, locking wall bracket	Free standing or double face adhesive tape	Holder with double face adhesive tape, locking wall bracket	Free standing	Same

Summary of technological characteristics

1) The same indication for 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;
5) complied with same performance testing standard.

Although the subject device and predicate device are different on size, dimensions, weight range, the differences in technological characteristics do not impair the subject devices from their intended functions of disposal and storage of sharp waste

9. Summary of Non-Clinical Tests :

Table 3: Non-Clinical Performance Testing

NO.	Test Name	Test Standards	Test Results
1	Container Stability	ISO23907-1:2019	Passed
2	Strength of Handles	ISO23907-1:2019	Passed
3	Resistance to penetration	ISO23907-1:2019	Passed
4	Resistance to damage and leakage after dropping	ISO23907-1:2019	Passed
5	Resistance to damage and leakage after toppling	ISO23907-1:2019	Passed
6	Stacking Test	49CFR 178.606	Passed
7	Vibration Test	49CFR 178.608	Passed
8	Leak proof on the sides and bottom	OSHA Regulations (Standards - 29 CFR) Bloodborne Pathogens. 1910.1030, (d)(2)(viii)(C)	Passed
9	Sharps access and closure for repeated openings and closings	Enterprise standards - Product Technical Requirements (Sharps container) GH-SG-002-1	Passed
10	Usable capacity test	Enterprise standards - Product Technical Requirements (Sharps container) GH-SG-002-1	Passed

10. Discussion of Clinical Tests Performed:

There was no clinical testing required to support the medical device.

11. Conclusions:

The conclusions drawn from the nonclinical tests demonstrate that the Guanhong Sharps Container (GHW-1F1); Guanhong Sharps Container (GHW-1F4); Guanhong Sharps Container (GH-6FA); Guanhong Sharps Container (GHW-2FR); Guanhong Sharps Container (GHW-8FR); Guanhong Sharps Container (GH-3FS); Guanhong Sharps Container (GHW-15FS); Guanhong Sharps Container (GHW-27FS); Guanhong Sharps Container (GH-5FSW); Guanhong Sharps Container (GHW-3FT); Guanhong Sharps Container (GHW-4FT); Guanhong Sharps Container (GHW-5FT); Guanhong Sharps Container (GHW-8FT); Guanhong Sharps Container (GH-9FY); Guanhong Sharps Container (GHW-3FY); Guanhong Sharps Container (GHW-5FY); Guanhong Sharps Container (GHW-2FY2); Guanhong Sharps Container (GHW-3FY2); Guanhong Sharps Container (GHW-5FY2); Guanhong Sharps Container (GH-1RA) subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K180984.