



October 15, 2025

Gcmedica Enterprise Ltd.(wuxi)
Adam Jiang
Quality Manager
18 Xinjin Road, Xinwu Industrial Zone
Wuxi, Jiangsu 214000
CHINA

Re: K251882
Trade/Device Name: Uterine Aspiration Set
Regulation Number: 21 CFR 884.1175
Regulation Name: Endometrial Suction Curette and accessories
Regulatory Class: II
Product Code: HHK
Dated: June 19, 2025
Received: September 12, 2025

Dear Adam Jiang:

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, Food and Drug Administration (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,

Jason Roberts -S

Jason R. Roberts, Ph.D.

Assistant Director

DHT3B: Division of Reproductive,

Gynecology, and Urology Devices

OHT3: Office of Gastrorenal, ObGyn,

General Hospital, and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K251882

Device Name
Uterine Aspiration Set

Indications for Use (Describe)

Uterine Aspiration Set is used with the vacuum system to aspirate transcervically the products of conception or menstruation from the uterus.

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

Uterine Aspiration Set

K251882

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

5.1 Submitter

Submitted by:	GCMEDICA ENTERPRISE LTD.(WUXI) 18 Xinjin Road, Xinwu Industrial Zone, Wuxi, 214000, China
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Date Prepared:	October 15, 2025

5.2 Device

Name of Device:	Uterine Aspiration Set
Common or Usual Name:	Uterine Aspiration Set

Name of Device:	Rigid Uterine Aspiration Curette
Common or Usual Name:	Intrauterine curette, suction
Classification Name:	Curette, Suction, Endometrial (And Accessories) (21 CFR 884.1175)
Regulatory Class:	II
Product Code:	HHK

Name of Device:	Flexible Uterine Aspiration Curette
Common or Usual Name:	Intrauterine curette, suction
Classification Name:	Curette, Suction, Endometrial (And Accessories) (21 CFR 884.1175)
Regulatory Class:	II
Product Code:	HHK

Name of Device:	Uterine Aspiration Tubing Set
Common or Usual Name:	Intrauterine curette, suction
Classification Name:	Curette, Suction, Endometrial (And

	Accessories) (21 CFR 884.1175)
Regulatory Class:	II
Product Code:	HHK

Name of Device:	Uterine Aspiration Tubing
Common or Usual Name:	Intrauterine curette, suction
Classification Name:	Curette, Suction, Endometrial (And Accessories) (21 CFR 884.1175)
Regulatory Class:	II
Product Code:	HHK

Name of Device:	Swivel Handle
Classification Name:	Curette, Suction, Endometrial (And Accessories) (21 CFR 884.1175)
Regulatory Class:	II
Product Code:	HHK

Note: Uterine Aspiration Tubing and Swivel Handle are components of the Uterine Aspiration Tubing Set.

5.3 Predicate Device

Berkeley® VC-10 Vacuum Curettage System, Berkeley® Vacurette® Cannulas and Cannulas(F-tips), Collection Tubing Set, K030935

The predicate device experienced one recall event due to a manufacturing process control issue. However, the recall was not related to the device design.

No reference devices were used in this submission.

5.4 General Device Description

The Uterine Aspiration Set consists of rigid/flexible uterine aspiration curette and uterine aspiration tubing set(Composed of uterine aspiration tubing, swivel handle and other components). Rigid/flexible uterine aspiration curette and uterine aspiration tubing set(including uterine aspiration tubing and swivel handle) are all disposable and supplied sterile.

Rigid/Flexible Uterine Aspiration Curette

The rigid/flexible uterine aspiration curette is mainly used to scrape and remove tissues in the endometrium or uterine cavity. Its tip is suitable for entering the uterine cavity and performing scraping operations.

Uterine Aspiration Tubing Set

The uterine aspiration tubing set is mainly used to generate negative pressure during the surgical

process. It is usually connected at one end to a Rigid/Flexible Uterine Aspiration Curette for scraping operations, and at the other end to a suction device, and tissues are sucked out by negative pressure. The suction force can be adjusted by sliding the ring on the vacuum control hole.

5.5 Indications for Use

Uterine Aspiration Set is used with the vacuum system to aspirate transcervically the products of conception or menstruation from the uterus.

5.6 Comparison of Technological Characteristics with the Predicate Device

The proposed device is compared with some components (Berkeley® Vacurette® Cannulas and Cannulas(F-tips), Collection Tubing Set) of the predicate device. It can be effectively connected with the suction device to generate a stable and adjustable negative pressure, so as to efficiently remove the uterine tissue and adapt to the uterine conditions of different patients.

The following tables (Table 5.6.1, Table 5.6.2, Table 5.6.3 and Table 5.6.4) are summaries of the uterine aspiration set technological characteristics as compared to the predicated device from ACMI CORPORATION.

Table 5.6.1 Summary of technological characteristics between proposed device Rigid Uterine Aspiration Curette and the predicate device Berkeley® Vacurette® Cannulas from ACMI CORPORATION

Item	Proposed Device	Predicated Device
Device name	Rigid Uterine Aspiration Curette	Berkeley® Vacurette® Cannulas
510(k) number	K251882	K030935
Manufacturer	GCMEDICA ENTERPRISE LTD.(WUXI)	ACMI CORPORATION
Product Code	HHK	HHK
Regulation No.	884.1175	884.1175
Classification	2	2
Intended use	The rigid or flexible Uterine Aspiration Curette is used for curettage and evacuation of the contents of the endometrium during induced termination of pregnancy or after miscarriage.	For rapid transcervical aspiration of the uterine cavity. (The intended use of the entire system)
Environment of Use	Hospital or clinics	Hospital or clinics
Supplied Sterile	Sterile	Sterile
Sterilization method	EO	EO
Compatibility	1. Devices that comply with ISO 10079-1; 2. Devices with a claimed maximum vacuum range of less than 98 kPa.	Gyrus ACMI Berkeley vacuum curettage system

Single Use	Yes	Yes
Material	SBC	Propionate, polyethylene
Sizes (mm)	6-12,14,16	7-12,14,16

Table 5.6.2 Summary of technological characteristics between proposed device Flexible Uterine Aspiration Curette and the predicate device Berkeley® Vacurette® Cannulas(F-Tip) from ACMI CORPORATION

Item	Proposed Device	Predicated Device
Device name	Flexible Uterine Aspiration Curette	Berkeley® Vacurette® Cannulas(F-Tip)
510(k) number	K251882	K030935
Manufacturer	GCMEDICA ENTERPRISE LTD.(WUXI)	ACMI CORPORATION
Product Code	HHK	HHK
Regulation No.	884.1175	884.1175
Classification	2	2
Intended use	The rigid or flexible Uterine Aspiration Curette is used for curettage and evacuation of the contents of the endometrium during induced termination of pregnancy or after miscarriage.	For rapid transcervical aspiration of the uterine cavity. (The intended use of the entire system)
Environment of Use	Hospital or clinics	Hospital or clinics
Supplied Sterile	Sterile	Sterile
Sterilization method	EO	EO
Compatibility	1. Devices that comply with ISO 10079-1 ; 2. Devices with a claimed maximum vacuum range of less than 98 kPa.	Gyrus ACMI Berkeley vacuum curettage system
Single Use	Yes	Yes
Material	ABS, LDPE	Propionate, polyethylene
Sizes (mm)	4-12	4-8

Table 5.6.3 Summary of technological characteristics between proposed device Uterine Aspiration Tubing Set and the predicate device Collection Tubing Set from ACMI CORPORATION

Item	Proposed Device	Predicated Device
Device name	Uterine Aspiration Tubing Set	Collection Tubing Set
510(k) number	K251882	K030935
Manufacturer	GCMEDICA ENTERPRISE LTD.(WUXI)	ACMI CORPORATION
Product Code	HHK	HHK

Regulation No.	884.1175	884.1175
Classification	2	2
Intended use	The Uterine Aspiration Tubing Set is designed for use in conjunction with a Uterine Aspiration Curette to enable suction/aspiration during the process of gynecological operations and provide more convenience for easier operation.	For rapid transcervical aspiration of the uterine cavity. (The intended use of the entire system)
Environment of Use	Hospital or clinics	Hospital or clinics
Supplied Sterile	Sterile	Sterile
Sterilization method	EO	EO
Compatibility	1. Devices that comply with ISO 10079-1 ; 2. Devices with a claimed maximum vacuum range of less than 98 kPa.	Gyrus ACMI Berkeley vacuum curettage system
Single Use	Yes	Yes
Material	SBC, PVC	PVC
tubing length	1.8m,2m,3m	6ft (1.8288m)

5.7 Non-Clinical Performance Data

GCMEDICA performed bench testing to support substantial equivalence. The following testing was performed on GCMEDICA samples from production lots, including sterilization.

Proposed Device	Bench Testing
Rigid Uterine Aspiration Curette	1. Appearance 2. Dimension 3. Connection Firmness 4. Leak Test 5. Print Fastness 6. Negative Pressure Test 7. Patency
Flexible Uterine Aspiration Curette	1. Appearance 2. Dimension 3. Connection Firmness 4. Leak Test 5. Print Fastness 6. Negative Pressure Test 7. Patency 8. Kink Resistance Testing
Uterine Aspiration Tubing Set	1. Appearance

	<ol style="list-style-type: none"> 2. Dimension 3. Negative Pressure Test 4. Leak Test 5. Connection Firmness
Uterine Aspiration Set	<ol style="list-style-type: none"> 1. Appearance 2. Dimension 3. Negative Pressure Test 4. Leak Test 5. Connection Firmness

5.7.1 Sterilization

The Uterine Aspiration Set consists of rigid/flexible uterine aspiration curette, uterine aspiration tubing set(Composed of uterine aspiration tubing, swivel handle and other components). The products are all sold in sterile packages. The Uterine Aspiration Set has been sterilized in a validated EO sterilization cycle. The EO sterilization cycle has a Sterility Assurance Level (SAL) of 10^{-6} . EO residuals on the Uterine Aspiration Set are below the maximum levels defined in ANSI/AAMI/ISO 10993-7:2008 Biological Evaluation of Medical Device - Part 7: Ethylene Oxide sterilization residuals. The Uterine Aspiration Set, and the predicate devices, are not labeled as pyrogen-free because they do not have any blood or cerebrospinal fluid contact. Rigid/flexible uterine aspiration curette, uterine aspiration tubing set and uterine aspiration set are packaged in a paper/film peel pouch like other sterile products GCMEDICA currently manufacture. These pouches have been tested by GCMEDICA and shown to provide and maintain a sterile barrier for at least five (5) years.

5.7.2 Shelf Life

The Uterine Aspiration Set has a five (5) years expiration date, based on the design and material equivalence to the predicated device and existing sterile barrier data from GCMEDICA existing packaging. The Uterine Aspiration Set is packaged in a paper/film peel pouch like other sterile products GCMEDICA currently manufacture. These pouches and products have been tested by GCMEDICA, including accelerated aging, seal strength, dye penetration, packaging persistence bacteria performance and shown to provide and maintain a sterile barrier for at least five (5) years. The Uterine Aspiration Set has been tested by GCMEDICA before and after accelerated aging test. The product's visual appearance, dimensions, and performance remained qualified for at least five (5) years.

5.8 Clinical Testing

Similar devices have been on the market for many years with proven safety and efficacy for the use of the device. These devices have no direct patient contact. Based on this history and the use of the device, clinical testing was not necessary to support substantial equivalence data. The non-clinical testing performed supports safety and efficacy of the device and provides data to show substantial equivalence to the predicated devices.

5.9 Biocompatibility

Biocompatibility studies were performed in accordance with the 2020 FDA guidance document “Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and “testing” and current applicable standards, as follows:

- Cytotoxicity: ISO 10993-5:2009
- Sensitization: ISO 10993-10:2010
- Irritation: ISO 10993-23:2021

5.10 Conclusion

Based on the technological characteristics and bench testing performance, GCMEDICA believes there are no significant differences between the Uterine Aspiration Set and the predicate devices.

The proposed device does not raise new issues regarding safety or effectiveness and is considered substantially equivalent to the predicate.