February 12, 2026

Guangzhou Hehong Biotech Co., Ltd.
Lena Liang
International Registration Specialist
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Shilou Town, Panyu District
Guangzhou, Guangdong 511447
CHINA

Re: K253354
Trade/Device Name: Minvitro Embryo Transfer Catheters (ETCA23175, ETCA23175-C, ETCB20175, ETCB20175-C, ETCB20175-ET, ETCB20175-ET-C)
Regulation Number: 21 CFR 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: II
Product Code: MQF
Dated: December 18, 2025
Received: December 18, 2025

Dear Lena Liang:

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: The Center for Devices and Radiological Health (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, the 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
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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)*
K253354

Device Name
Minvitro Embryo Transfer Catheters (ETCA23175, ETCA23175-C, ETCB20175, ETCB20175-C, ETCB20175-ET, ETCB20175-ET-C)

Indications for Use *(Describe)*
Minvitro Embryo Transfer Catheters are used to place in vitro fertilized (IVF) embryos into the uterine cavity.

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
K253354

Submitted by:

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Submission Correspondent:	Lena Liang International Registration Specialist Guangzhou Hehong Biotech Co., Ltd. (liangxiaoqing@huayueco.com)

Date prepared: February 11, 2026

1. Subject Device

Trade Name:	Minvitro Embryo Transfer Catheters (ETCA23175, ETCA23175-C, ETCB20175, ETCB20175-C, ETCB20175-ET, ETCB20175-ET-C)
Common Name:	Embryo Transfer Catheter
Regulation Name:	Assisted Reproduction Catheters
Regulation Number:	21 CFR 884.6110
Regulatory Class:	II
Product Code:	MQF (Catheter, Assisted Reproduction)

2. Predicate Device

Kitazato ET Catheters (K162878) manufactured by Kitazato Corporation.

The predicate device has not been subject to a design-related recall.

3. Device Description

Minvitro Embryo Transfer Catheters are sterile single-use catheters used to place in vitro fertilized embryos into the uterine cavity. All the models of Minvitro Embryo Transfer Catheters have a transfer catheter and a guide catheter. A stylet is an optional accessory for specific models.

The guide catheter is delivered through the cervix first and is used to guide the insertion of the transfer catheter

holding the embryos into the uterine cavity. Two versions of guide catheters are provided:

- ETCA23175 series: Straight echogenic guide, with catheter shaft detectable under ultrasound to aid in catheter placement.
- ETCB20175 series: Pre-curved guide with a bulb tip and an adjustable positioner to facilitate proper positioning.

The transfer catheter is loaded with embryos and inserted into the guide catheter. Embryos are delivered into the uterine cavity by pressing a syringe (not provided with the catheters) connected to the transfer catheter's hub. The transfer catheter features a reinforced stainless steel support tube, with graduation marks printed on its proximal shaft. Variations with an additional echotip at the end of transfer catheter are offered for specific models (ETCB20175-ET and ETCB20175-ET-C) to assist visualization under ultrasound.

The stylet is an optional accessory for specific models. It is a malleable plastic-coated stainless steel core, which is used to provide additional rigidity and support during guide catheter insertion.

Device model specifications for the Minvitro Embryo Transfer Catheters are shown below.

Model	Device component (features)		
	Guide catheter	Transfer catheter	Stylet
ETCA23175	OD 2.30 mm, Length 17.5 cm Straight, echogenic	OD 0.95 mm, Length 24.3 cm	N/A
ETCA23175-C	OD 2.30 mm, Length 17.5 cm Straight, echogenic	OD 0.95 mm, Length 24.3 cm	Length 20.3 cm
ETCB20175	OD 2.30 mm, Length 17.5 cm Pre-curved, bulb tip & positioner	OD 0.95 mm, Length 24.3 cm	N/A
ETCB20175-C	OD 2.30 mm, Length 17.5 cm Pre-curved, bulb tip & positioner	OD 0.95 mm, Length 24.3 cm	Length 20.3 cm
ETCB20175-ET	OD 2.30 mm, Length 17.5 cm Pre-curved, bulb tip & positioner	OD 0.95 mm, Length 24.3 cm, With Echotip	N/A
ETCB20175-ET-C	OD 2.30 mm, Length 17.5 cm Pre-curved, bulb tip & positioner	OD 0.95 mm, Length 24.3 cm, With Echotip	Length 20.3 cm

4. Indications for Use Statement

Minvitro Embryo Transfer Catheters are used to place in vitro fertilized (IVF) embryos into the uterine cavity.

5. Comparison of Intended Use and Technological Characteristics of the Subject Device and Predicate Device

Parameter	Subject Device K253354	Predicate Device K162878	Equivalence
Manufacturer	Guangzhou Hehong Biotech Co., Ltd	Kitazato Corporation	N/A
Device Name	Minvitro Embryo Transfer Catheters	Kitazato ET Catheters	N/A
Model	ETCA23175, ETCA23175-C, ETCB20175, ETCB20175-C, ETCB20175-ET, ETCB20175-ET-C	Type 2 EC-PRO Supported [Version 2 and 8], Type 4 EC-PRO Master Supported [Version 2 and 8], Type 5 Stylet Cannula [Version 2]	N/A
Product Code	MQF	MQF	Same
Regulation	884.6110	884.6110	Same
Indication for Use	Minvitro Embryo Transfer Cathers are used to place in vitro fertilized (IVF) embryos into the uterine cavity.	The Kitazato ET Catheters are intended for ultrasound guided introduction of embryos into the uterine cavity following in vitro fertilization. Kitazato ET Catheters are provided in various configurations (Type 1 through Type 5), which consist of the following components: • Transfer Catheter, for delivery of embryos into the uterine cavity; • Guide Catheter, to guide the insertion of the Transfer Catheter and reinforce it during use; • Trial Catheter, used to confirm the curvature of the cervix and if the cervix is passable; • Stylet Sheath, used to increase the strength of the Guide Catheter during insertion.	**Different.**

Parameter	Subject Device K253354	Predicate Device K162878	Equivalence
Design features	Transfer catheter: • Open-end shaft with depth marks and protective sleeve • Luer connector • Outer supporting tube (stiffener) • With or without echogenic band on the tip (Echotip) Guide catheter: • Echogenic straight shaft with depth marks (ETCA23175 series) • Pre-curved shaft with depth marks, a positioner and bulb-tip design (ETCB20175 series) • Handle	Transfer catheter: • Open-end shaft with depth marks and protective sleeve • Luer connector • Outer stiffener • Echo line Guide catheter: • Straight or curved shaft with depth marks • Handle/connector Trial: Same as corresponding size transfer catheter, but with closed end.	**Different.**
Inclusion of a stylet	Yes (ETCA23175-C, ETCB20175-C, ETCB20175-ET-C)	Yes (Type 5)	Same
Dimension	Transfer catheter: Length 24.3 cm OD 0.95 mm (2.85 Fr) Guide catheter: Length 17.5 cm OD 2.30 mm (6.9 Fr)	Catheter length: 18 and 23 cm Catheter outer diameter: 1.55 mm / 4.7 Fr Guide length: 14 and 19 cm	**Different.**
Material	Transfer catheter: Polyethylene (PE), thermoplastic polyurethane (TPU), stainless steel, platinum-iridium alloy, printing ink Pre-curved guide: PEBAX, silicone, PE, printing ink Straight guide: Polyurethane (PU), PE, printing ink	Catheter shaft: Polyurethane Guide: Fluoric resin Luer connector: ABS Outer stiffener: Stainless steel	**Different.**
Sterilization method	Electron beam irradiation	Ethylene oxide (ETO)	**Different.**
Single Use	Yes	Yes	Same

Parameter	Subject Device K253354	Predicate Device K162878	Equivalence
Shelf-life	2 years	3 years	**Different.**
Mouse Embryo Assay	One-cell system ≥80% embryos developed to blastocyst in 96 hours	1-cell, ≥80% expanded blastocysts at 96 hours	Same.
Endotoxin	< 20 EU/device	< 20 EU/device	Same.

Despite differences in their indication for use statements, the subject device and the predicate device have the same intended use (i.e., transfer of embryos into the uterine cavity). As shown above, the subject device and predicate device have different technological characteristics, including differences in design features, materials, dimension, sterilization method and shelf life; however, the differences noted do not raise different questions of safety and effectiveness.

6. Summary of Non-Clinical Performance Data

The following studies have been performed to support of the substantial equivalence to the predicate device:

- **Sterilization validation testing** per ISO 11137-1:2006 and ISO 11137-2:2013
- **Transportation Simulation testing** per ASTM D4169-22
- **Packaging integrity testing**:
    - Visual inspection per ASTM F1886/F1886M-16
    - Seal Strength testing per ASTM F88/ F88M-23
    - Dye Penetration test per ASTM F1929-23
- **Biocompatibility evaluation** conducted in accordance with the 2023 FDA guidance, *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices — Part 1: Evaluation and testing within a risk management process*." Testing included the following assessments:
    - Cytotoxicity per ISO 10993-5: 2009
    - Sensitization ISO 10993-10: 2021
    - Irritation per ISO 10993-23: 2021

  Testing showed the device material to be non-cytotoxic, non-sensitizing, and non-irritating.
- **Endotoxin testing** conducted before and after aging per USP <85> with acceptance criteria: <20 EU/device.
- **Mouse embryo assay (MEA)** conducted before and after aging per the 2021 FDA guidance, *Mouse Embryo Assay for Assisted Reproduction Technology Devices* with specification: One-cell System ≥80% embryos developed to blastocyst in 96 hours.
- **Bench performance** conducted before and after accelerated aging to the equivalent of two (2) years of real-time aging in accordance with ASTM F1980-21 demonstrated that all predetermined acceptance

criteria were met in the following tests:

- Appearance
- Dimension verification
- Transfer catheter and stylet compatibility with guide catheter
- Depth mark location and color-fastness
- Tensile strength of catheter shaft
- Bonding strength of device connections
- Dislodgement of positioner
- Tip drop when held horizontally
- Removal force of Echotip
- Ultrasound visibility
- Verification of luer hub
- Aspiration, leakage, and flow rate of transfer catheter
- Corrosion resistance, toughness and stiffness of stainless steel support tube

7. Conclusion

The results of the testing described above demonstrate that Minvitro Embryo Transfer Catheters are as safe and effective as the predicate device and supports a determination of substantial equivalence.