February 3, 2025

Guangzhou Hehong Biotech Co., Ltd.
% Melody Huang
Regulatory Consultant
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K241454
Trade/Device Name: Minvitro® Vitrification Straw (MVT-VSN series: MVT-VSNR, MVT-VSNY, MVT-VSNB, MVT-VSNG, MVT-VSNP)
Regulation Number: 21 CFR 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: II
Product Code: MQK
Received: January 2, 2025

Dear Melody Huang:

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,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
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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)*
K241454

Device Name
Minvitro® Vitrification Straw (MVT-VSN series: MVT-VSNR, MVT-VSNY, MVT-VSNB, MVT-VSNG, MVT-VSNP)

Indications for Use *(Describe)*
The Minvitro® Vitrification Straw (MVT-VSN series: MVT-VSNR, MVT-VSNY, MVT-VSNB, MVT-VSNG, MVT-VSNP) is a cryopreservation storage device intended for use in vitrification procedures to contain and maintain human oocytes (MII), 4-8 cell embryos, and blastocyst stage embryos.

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
K241454

1. Submitter Information

Applicant:	Guangzhou Hehong Biotech Co., Ltd.
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2. Submission Correspondent

Contact:	Melody Huang
Phone:	86 (138) 236-02134
Email:	melody36025@126.com

3. Date prepared: January 31, 2025

4. Device Information

Device Name:	Minvitro® Vitrification Straw (MVT-VSN series: MVT-VSNR, MVT-VSNY, MVT-VSNB, MVT-VSNG, MVT-VSNP)
Common Name:	Cryopreservation Storage Device
Regulation Number:	21 CFR 884.6160
Regulation Name:	Assisted Reproduction Labware
Product Code:	MQK (Labware, Assisted Reproduction)
Regulatory Class:	Class II

5. Predicate Device Information

Device Name:	Cryotop® US-flash
510(k) Number:	K181469
Sponsor:	Kitazato Corporation.

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

6. Device Description

The Minvitro® Vitrification Straw (MVT-VSN series: MVT-VSNR, MVT-VSNY, MVT-VSNB, MVT-VSNG, MVT-VSNP) are intended for use in closed vitrification procedures to contain and maintain human oocytes (MII), 4-8 cell embryos, and blastocyst stage embryos, and they are intended for use in professional healthcare facilities. The subject devices are for single use, disposable and supplied sterile.

The Minvitro® Vitrification Straws (MVT-VSN series: MVT-VSNR, MVT-VSNY, MVT-VSNB,

MVT-VSNG, MVT-VSNP) are all composed of a cap with a balancing head, a handle, a carrier sheet with a fine tip at the end. The oocytes or embryos are loaded on the carrier sheet, and in which, the fine tip of carrier sheet is flat with a triangular-shaped area for oocyte/embryo loading. The subject devices are sterilized using ethylene oxide (EO) to a sterilization assurance level of 10^{-6}, are single-use, and have a 2-year shelf-life.

The subject devices are available in five colors: MVT-VSNR, MVT-VSNY, MVT-VSNB, MVT-VSNG, and MVT-VSNP corresponding to Red, Yellow, Blue, Green, and Purple, respectively, all identical in size.

7. Indications for Use Statement

The Minvitro® Vitrification Straw (MVT-VSN series: MVT-VSNR, MVT-VSNY, MVT-VSNB, MVT-VSNG, MVT-VSNP) is a cryopreservation storage device intended for use in vitrification procedures to contain and maintain human oocytes (MII), 4-8 cell embryos, and blastocyst stage embryos.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below includes a comparison of the intended use and technological characteristics of the subject and predicate devices.

	K241454	**K181469**	**Comparison**
Regulation Number	21 CFR 884.6160	21 CFR 884.6160	Same
Product Code	MQK	MQK	Same
Classification	Class II	Class II	Same
Indications for Use	The Minvitro® Vitrification Straw (MVT-VSN series: MVT-VSNR, MVT-VSNY, MVT-VSNB, MVT-VSNG, MVT-VSNP) is a cryopreservation storage device intended for use in vitrification procedures to contain and maintain human oocytes (MII), 4-8 cell embryos, and blastocyst stage embryos.	Cryotop® US-flash are cryopreservation storage devices that are intended for use in vitrification procedures to contain and maintain human oocytes (MII) and embryos.	**Different**
Design	A handle incorporating a	A handle incorporating a	Same

	sample-loading tip, and a cap to close the device.	sample-loading tip, and a cap to close the device.	
Film Tip shape	Flat	Flat	Same
Dimensions	Total length – 131 mm Carrier sheet length – 22 mm Handle length – 84 mm Cap length – 80 mm Cap diameter – 2.9 mm	Total length – 116 mm Film tip/carrier sheet length – 18 mm Handle length – 98 mm Straw/cap length – 90 mm Straw/cap diameter – 3 mm	**Different**
Marks/etching	Marks on distal tip end, on body of the stick and at the opening of the cap	Marks on distal tip end, on body of the handle and at the opening of the cap	Same
Materials	Handle – acrylonitrile butadiene styrene (i.e. ABS) Carrier Sheet and Fine tip – Polyethylene Terephthalate Glycol (i.e. PETG) Cap –Polyethylene Terephthalate Glycol (i.e. PETG) Cap balancing head – SUS 304 stainless steel	Handle – acrylonitrile butadiene styrene Fine tip – polyethylene terephthalate Straw/cap – polypropylene/stainless steel	**Different**
Vitrification system	Closed	Closed	Same
Cooling rate (closed cap)	-3000 ºC/min	-3000ºC/min	Same
Warming rate (closed cap)	40000 ºC/min	44000 ºC/min	**Different**
Single use	Yes	Yes	Same
Sterilization method	Ethylene Oxide	Gamma	**Different**
Sterilization assurance level	SAL 10^{-6}	SAL 10^{-6}	Same
Endotoxin tested	Endo LAL, ≤ 0.5 EU/device	Endo LAL, ≤ 0.5 EU/device	Same
MEA testing	One-Cell System: ≥80% embryos developed to expanded blastocyst at 96 hours	Mouse Embryo Assay (1-Cell to Blastocyst at 96h ≥ 80%)	**Different**

As shown in the table above, there are differences in the subject and predicate device indications for use statements; however, they have the same intended use (i.e., vitrification and storage of human oocytes (MII), 4-8 cell embryos, and blastocyst stage embryos).

The subject and predicate devices also have differences in technological characteristics, including different warming rates, material composition, and dimensions. These technological differences do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Sterilization Testing:
Sterilization information was provided in accordance with the 2016 FDA guidance "Submission and Review of Sterility Information in Premarket Notification (510(k) Submissions for Devices Labeled as Sterile." The subject devices are subjected to an Ethylene Oxide (EO) process to achieve a Sterility Assurance Level (SAL) of 10^{-6}. The sterilization cycle was validated in accordance with ISO 11135:2014, ISO 11607-1-2006/Amd 1-2014, ISO 11607-2-2006/Amd 1-2014, ISO 11737-1:2018, ISO 11737-2:2009, ISO 11138-2:2017, ISO 10993-7:2008/Cor 1-2009.

Simulated Transportation and conditioning:
Simulated transportation per ASTM D4169-22 and environmental conditioning per ASTM D4332-22 were performed after accelerated aging per ASTM D4169-22.

Endotoxin
Evaluation performed on unaged devices using the Gel-Clot Limulus Amoebocyte Lysate (LAL) method per USP <85>. The acceptance criterion was ≤ 0.5 EU/device.

Cooling/warming rate
A comparative analysis was provided on unaged and accelerated aged subject devices against the predicate device, K181469, to verify cooling/warming rates for closed vitrification storage after immersion and removal from liquid nitrogen. The subject device performed within the specifications noted in the table above.

Stability and Shelf Life:
The following tests were completed to demonstrate that the subject devices maintained their performance in newly manufactured devices and after 2-years of accelerated aging per ASTM F1980-21 and simulated transportation/conditioning:

- Mouse embryo assay (MEA) – Testing conducted in accordance with the 2021 FDA guidance "Mouse Embryo Assay for Assisted Reproduction Technology Devices." The acceptance criterion for the 1-Cell MEA was ≥80% embryos expanded to blastocyst at 96 hours.
- Package Integrity Testing:
  - F1886/F1886M-16
  - ASTM F88/F88M-15
  - ASTM F1929-15

- Mechanical Performance Testing:
  - Dimensional testing
  - Examination following cryostorage
  - Seal integrity and leakage assessment following cryostorage
  - Capping force and torque testing
  - Uncapping force and torque testing

10. Conclusion

The results of the performance testing described above demonstrate that the subject devices are as safe and effective as the predicate device and support a determination of substantial equivalence.