May 11, 2023

Zhejiang Horizon Medical Technology Co., Ltd
Wu Tang
RA Supervisor
Rom 219, 2nd floor, Building 9, 1303 Asia-Pacific Road,
Daqiao Town, Nanhu District
Jiaxing, Zhejiang 314006
China

Re: K223265
Trade/Device Name: CryoX™ Vitrification Freeze Kit / Thaw Kit
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: April 7, 2023
Received: April 7, 2023

Dear Wu Tang:

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 (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 located 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.

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

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

Michael T. Bailey -S

For
Monica D. Garcia, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223265

Device Name
CryoX™ Vitrification Freeze Kit / Thaw Kit

Indications for Use *(Describe)*
CryoXTM Vitrification Freeze Kit is intended for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

CryoXTM Vitrification Thaw Kit is intended for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage 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.

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510(k) Summary
K223265

I. SUBMITTER

Applicant: Zhejiang Horizon Medical Technology Co., Ltd.

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Contact Person: Wu Tang, RA Supervisor

Email: Wu.Tang@microport.com

Date Prepared: May 8, 2023

II. DEVICE

Trade Name: CryoX™ Vitrification Freeze Kit / Thaw Kit

Common Name: Assisted Reproduction Media

Regulation Name: Reproductive Media and Supplements

Regulation Number: 884.6180

Product Code: MQL (Media, Reproductive)

Regulatory Class: II

III. PREDICATE DEVICE

Vit Kit-Freeze NX and Vit Kit-Warm NX (K190152) from FUJIFILM Irvine Scientific, Inc.

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

IV. DEVICE DESCRIPTION

CryoX™ Vitrification Freeze Kit is designed to facilitate dehydration of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos before vitrification via rapid cooling in liquid nitrogen. CryoX™ Vitrification Freeze Kit contains two solutions to be used sequentially during vitrification. Both solutions consist of Medium 199 (M199), human serum albumin (HSA) and gentamicin sulfate. They also contain varying levels of cryoprotectants, including dimethyl sulfoxide (DMSO), ethylene glycol (EG), and sucrose.

CryoX™ Vitrification Thaw Kit contains three solutions to be used sequentially during oocyte and embryo thawing procedures. All three solutions contain M199, HSA, and gentamicin sulfate. They also contain decreasing concentrations of cryoprotectant.

The five solutions in the CryoX™ Vitrification Freeze Kit and Thaw Kit are aseptically filtered and provided in 4.5 mL PETG vials. The solutions in these kits are single-use only. They have a shelf-life of 6 months when stored at 2-8°C

V. INDICATIONS for USE

CryoX™ Vitrification Freeze Kit is intended for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

CryoX™ Vitrification Thaw Kit is intended for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos.

VI. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A comparison of the intended use and technological features of the subject and predicate devices are described in the table below:

Comparison Item	K223265 Subject Device	K190152 Predicate Device	Comparison
Indication for Use	CryoX™ Vitrification Freeze Kit is intended for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos. CryoX™ Vitrification Thaw Kit is intended for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage	Vit Kit - Freeze NX (Vitrification Freeze Kit) is intended for use in the vitrification of oocytes (MII) and pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos. Vit Kit – Warm NX (Vitrification Warm Kit) is intended for use in the thawing of vitrified oocytes (MII) and pronuclear (PN) zygotes	There are differences in the wording of the indications for use statements for the subject and predicate device; however, the intended uses of the subject and predicate devices are the same.

Comparison Item	K223265 Subject Device	K190152 Predicate Device	Comparison
	embryos, and blastocyst stage embryos.	through day 3 cleavage stage embryos and blastocyst stage embryos.	
Conditions for Use	Prescription Use Only	Prescription Use Only	**Same**
Freeze Kit Formulation	M199 (HEPES buffer) Sucrose (0.5M) EG (7.5%, 15%) DMSO (7.5%, 15%) HSA Gentamicin Sulfate	CSCM (HEPES and MOPS buffer) Trehalose (0.5M) EG (7.5%, 15%) DMSO 7.5%, 15% HSA Gentamicin Dextran Substitute Supplement Sodium Bicarbonate	**Different:** The formulations of the subject and predicate devices are not the same. Differences in device formulations do not raise different questions of safety and effectiveness (S&E).
Thaw Kit Formulation	M199 (HEPES buffer) Sucrose (0.5 M, 1M) HSA Gentamicin Sulfate	CSCM (HEPES and MOPS buffer) Trehalose (0.5M, 1.0M) HSA Gentamicin Dextran Substitute Supplement Sodium Bicarbonate	**Different:** The formulations of the subject and predicate devices are not the same. Differences in device formulations do not raise different questions of S&E.
pH	ES: 7.2- 7.6 VS: 7.2- 7.6 TS: 7.2- 7.6 DS: 7.2- 7.6 WS: 7.2- 7.6	ES: 7.05 - 7.44 VS: 7.05 - 7.44 TS: 7.05 - 7.45 DS: 7.05 - 7.45 WS: 7.05 - 7.45	**Different:** The subject device has a higher pH range than the predicate device. These differences in pH specifications do not raise different questions of S&E.
Osmolality (mOsmol/kg)	ES: 855~1042 (1:2 dilution) VS: 1916~2477 (1:2 dilution)	ES: 1150 - 1550 VS: 1220 - 1620 TS: 1550 - 1900 DS: 830 - 930	**Different:** The subject device and predicate devices have differences in osmolality specifications.

Comparison Item	K223265 Subject Device	K190152 Predicate Device	Comparison
	TS: 1653~2430 DS: 871~1025 WS: 307~318	WS: 265 - 300	These differences in osmolality specifications do not raise different questions of S&E.
Bacterial Endotoxin	< 0.5 EU/mL	≤ 0.6 EU/mL	**Different:** The subject device has a lower endotoxin specification than the predicate device. This difference in endotoxin specification does not raise different questions of S&E.
Mouse Embryo Assay	1-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours.	1-Cell MEA: ≥ 80% expanded blastocyst after 96 hours in culture	**Same**
Sterilization Method	Aseptic Filtration	Aseptic Filtration	**Same**
Shelf-Life	6 months	12 months	**Different:** The subject device has a shorter shelf-life than the predicate device. Differences in shelf-life do not raise different questions of S&E.

As shown in the table above, there are differences in the indications for use statements and technological characteristics of the subject and predicate devices. However, as stated in the table, the differences in indications for use do not represent a new intended use and the differences in technological characteristics do not raise different questions of safety and effectiveness.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

The following studies have been conducted in support of the substantial equivalence to the predicate device.

- Aseptic filtration and aseptic filling validation, per ISO 13408-1:2008 & A1:2013 and ISO 13408-2:2018.

- Shelf-life testing was conducted to support a 6-month shelf-life for the subject device through demonstration that the product specifications (shown below) were met at time 0 and after accelerated aging in accordance with ASTM F1980-16:
  - Appearance: Clean, transparent, pink; no impurities
  - pH per USP <791>: 7.2-7.6
  - Osmolality per USP <785>: 855~1042 mOsmol/kg for ES (1:2 dilution); 1916-2477 mOsmol/kg for VS (1:2 dilution); 1653~2430 mOsmol/kg for TS; 871~1025 mOsmol/kg for DS; 307-318 mOsmol/kg for WS
  - Sterility per USP <71>: No microbial growth
  - Bacterial endotoxin per USP <85>: < 0.5 EU/mL
  - MEA per the 2021 FDA guidance *Mouse Embryo Assay for Assisted Reproduction Technology Devices*: 1-Cell MEA: ≥ 80%embryos developed to expanded blastocyst at 96 hours.
- Transportation testing per ASTM D4169-22 and cap/seal leak testing using a method equivalent to USP <1207.2> on transportation-conditioned devices.

VIII. CONCLUSION

The results of the performance testing described above demonstrate that CryoX™ Vitrification Freeze Kit / Thaw Kit is as safe and effective as the predicate device and supports a determination of substantial equivalence.