August 27, 2024

ECMPC, LLC
% Sarah Fitzgerald
Senior Consultant
Emergo by UL
2500 Bee Cave Road
Building 1, Suite 300
Austin, Texas 78746

Re: K233846
Trade/Device Name: Vitrification Solution Set and Warming Solution Set (Models 120, 210, 220)
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: July 31, 2024
Received: July 31, 2024

Dear Sarah Fitzgerald:

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.

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,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233846

Device Name
Vitrification Solution Set and Warming Solution Set, Models: 120, 210, 220

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

The Warming Solution Set 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 - K233846

Vitrification Solution Set and Warming Solution Set

1. Submitter

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3. Date Prepared

August 21, 2024

4. Device Identification

Trade Name: Vitrification Solution Set and Warming Solution Set (Models 120, 210, 220)
Common Name: Vitrification Cryopreservation Media
Regulatory Class: Class II
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Product Code: MQL

5. Predicate Device

Vitrification Kit and Thawing Kit (K171748) by Kitazato Corporation

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

6. Device Description

The Vitrification Solution Set and Warming Solution Set are intended for freezing and thawing oocytes and embryos for use in assisted reproductive technology (ART) procedures.

The Vitrification Solution Set consists of two media components, the Equilibration Solution (ES) and the Vitrification Solution (VS). The Warming Solution Set consists of three media components, the Thawing / Warming Solution (TS), Diluent Solution (DS), and Washing Solution (WS). All media are provided in 1.8 ml polypropylene vials with a polyethylene cap. All media in both sets undergo aseptic filtration and are single-use only.

7. Indication for Use

The Vitrification Solution Set is intended for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

The Warming Solution Set is intended for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos.

8. Substantial Equivalence Discussion

A comparison of the intended use and technological characteristics of the subject device and the predicate device is shown in the table below:

Attribute	**Subject: Vitrification Solution Set and Warming Solution Set (K233846)**	**Predicate: Vitrification Kit and Thawing Kit (K171748)**	**Comparison**
Indications for Use	The Vitrification Solution Set is intended for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos. The Warming Solution Set is intended for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos.	The Vitrification Kit is indicated for use in the preparation, vitrification and storage of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos. The Thawing Kit is indicated for use in the preparation and thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos.	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.
Sets / Components	Vitrification Media Warming Media	Vitrification Media Thawing Media Cryotop Repro Plate 35 mm dish	**Different:** The components of the subject and predicate devices are not the same.

Attribute	Subject: Vitrification Solution Set and Warming Solution Set (K233846)	Predicate: Vitrification Kit and Thawing Kit (K171748)	Comparison
			Differences in device components do not raise different questions of safety and effectiveness (S&E).
Embryo Stage	Oocyte, PN through Blastocyst	Oocyte, PN through Blastocyst	Same
Vitrification Media Components	2 – equilibration solution, vitrification solution	3 – basic solution, equilibration solution, vitrification solution	**Different:** The number of vitrification media of the subject and predicate devices are not the same. Differences in vitrification solutions do not raise different questions of S&E.
Warming Media Components	3 – thawing solution, diluent solution, washing solution	3 –thawing solution, diluent solution, washing solution	Same
Vitrification Formulation	HEPES HEPES sodium salt Ethylene glycol Dimethyl sulfoxide Trehalose Hydroxypropyl cellulose Gentamicin Minimum Essential Medium Polyvinylpyrrolidone Sodium bicarbonate	Medium 199 HEPES Ethylene glycol Dimethyl sulfoxide Trehalose Hydroxypropyl cellulose Gentamicin	**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.
Warming / Thawing Formulation	HEPES HEPES sodium salt Hydroxypropyl cellulose Trehalose Minimum Essential Medium Polyvinylpyrrolidone Sodium bicarbonate Gentamicin	Medium 199 HEPES Hydroxypropyl cellulose Trehalose Gentamicin	
Sterilization	Aseptic filtration	Aseptic filtration	Same
Sterility	No growth	Passes USP <71>	Same
Endotoxins	≤ 0.5 EU/ml (LAL)	< 0.25 EU/ml (LAL)	**Different:** The endotoxin specification of the subject and predicate devices are not the same. Differences in the stated

Attribute	Subject: Vitrification Solution Set and Warming Solution Set (K233846)	Predicate: Vitrification Kit and Thawing Kit (K171748)	Comparison
			endotoxin specifications do not raise different questions of S&E.
Mouse Embryo Assay (MEA)	≥ 80% embryos developed to expanded blastocyst at 96 hours	≥ 80% development to blastocyst at 96 hours	Similar
pH	7.20 – 7.60	7.20 – 7.60	Same
Osmolality (mOsm/kg)	ES: 2348-2596 VS**:** 2316-2559 after 1:1 dilution TS: 1613-1782 DS: 831-928 WS: 261-289	Not available	**Different:** The osmolality specification of the subject and predicate devices are not the same. Differences in osmolality do not raise different questions of S&E.
Storage	2-8°C	2-8°C	Same
Packaging	Each solution is contained in 1.8 mL polypropylene (PP) container and polyethylene (PE) screw caps molded with a thermoplastic elastomer (TPE) layer.	Each solution is contained in 1.5 mL or 4 mL plastic vials.	**Different:** The packaging of the subject and predicate devices are not the same. Differences in packaging do not raise different questions of S&E.
Shelf-Life	1 year	1 year	Same

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.

9. Summary of Non-Clinical Performance Testing

To demonstrate safety and effectiveness of the Vitrification Solution Set and Warming Solution Set and to show substantial equivalence to the predicate device, the following non-clinical tests have been performed.

- Aseptic processing and validation testing that met the requirements of ISO 13408-1:2008/Amd1:2013 and ISO 13408-2:2018. Testing was conducted on the subject device containing no antimicrobials.
- Shelf-life testing was conducted to support a one-year shelf-life for the subject devices through demonstration that the product specifications (shown below) were met at time 0 and after accelerated aging per ASTM F1980:21:
  - Sterility per USP <71>: No growth

  - Endotoxin per USP <85>: ≤ 0.5 EU/mL
  - pH per USP <791>: 7.2-7.6 for all solutions
  - Osmolality per USP <785>: see the table above for acceptance specifications
  - Mouse embryo assay per FDA guidance “Mouse Embryo Assay for Assisted Reproduction Technology Devices” (2021): One-cell system: ≥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.

10. Conclusion

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