August 26, 2025

Kitazato Corporation
% Mei Li
Quality and Regulatory Affairs Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road Building 1, Suite 300
Austin, Texas 78746

Re: K251305
Trade/Device Name: Ultra-Fast Vitri; Ultra-Fast Warm
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media And Supplements
Regulatory Class: Class II
Product Code: MQL
Dated: March 27, 2025
Received: July 29, 2025

Dear Mei Li:

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,
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)*
K251305

Device Name
Ultra-Fast Vitri; Ultra-Fast Warm

Indications for Use *(Describe)*
Ultra-Fast Vitri is indicated for use in the preparation, vitrification and storage of oocytes (MII).
Ultra-Fast Warm is indicated for use in the preparation and warming of vitrified oocytes(MII).

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 – K251305

Ultra-Fast Vitri; Ultra-Fast Warm

1. Submission Sponsor

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2. Submission Correspondent

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Contact: Mei Li
Title: Quality and Regulatory Affairs Consultant

3. Date Prepared

August 26, 2025

4. Device Identification

Trade/Proprietary Name:	Ultra-Fast Vitri; Ultra-Fast Warm
Common Name:	Vitrification and warming media for vitrified oocytes
Regulation Name:	Reproductive media and supplements
Regulation Number:	884.6180
Product Code:	MQL, Reproductive Media and Supplements
Class:	Class II
Classification Panel:	Obstetrics/Gynecology

5. Legally Marketed Predicate Device(s)

Device name: Vitrification Kit and Thawing Kit
510(k) number: K171748

Manufacturer: Kitazato Corporation

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

6. Device Description

The Ultra-Fast Vitri and Ultra-Fast Warm is composed of a set of three media to vitrify and warm oocytes for assisted reproductive technology (ART) procedures.

The Ultra-Fast Vitri includes two components, Equilibration Solution (ES) and Vitrification Solution (VS), containing the cryoprotectants ethylene glycol and dimethyl sulfoxide. There are two vitrification procedures to choose from. During the vitrification process, oocytes are first exposed to ES then in VS within several minutes. Using this methodology, permeating cryoprotectants can replace water in the oocytes prior to vitrification and storage in liquid nitrogen. The Ultra-Fast Vitri comes prepackaged with 1.5 mL vial or 4 mL vial of ES, three 1.5 mL vials or three 4 mL vials of VS.

Ultra-Fast Warm is composed of one media used for warming and removing cryoprotectants from vitrified oocytes. It is composed of Thawing Solution (TS). The Ultra-Fast Warm comes pre-packaged with four 4.0 ml vials of TS.

All the media in the Ultra-Fast Vitri and Ultra-Fast Warm contain Gentamicin. The media undergoes aseptic filtration, while the vials are sterilized by radiation.

7. Indication for Use Statement

Ultra-Fast Vitri is indicated for use in the preparation, vitrification and storage of oocytes (MII).

Ultra-Fast Warm is indicated for use in the preparation and warming of vitrified oocytes (MII).

8. Substantial Equivalence Discussion

The following table compares the Ultra-Fast Vitri and Ultra-Fast Warm to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any different questions of safety or effectiveness as compared to the predicate device.

Comparison of Characteristics

Feature	Subject Device: Ultra-Fast Vitri and Ultra-Fast Warm	Predicate: Vitrification Kit and Thawing Kit (K171748)
Device Classification	Class II Media, Reproductive	Class II Media, Reproductive
Product Code	MQL	MQL, MQK
Regulation No.	21 CFR 884.6180	21 CFR 884.6180
Manufacturer	Kitazato Corporation	Kitazato Corporation
Intended Use	Reproductive media and supplements	Reproductive media and supplements

Feature	Subject Device: Ultra-Fast Vitri and Ultra-Fast Warm	Predicate: Vitrification Kit and Thawing Kit (K171748)
Indications for Use	Ultra-Fast Vitri is indicated for use in the preparation, vitrification and storage of oocytes (MII).	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.
	Ultra-Fast Warm is indicated for use in the preparation and warming of vitrified oocytes (MII).	The Thawing Kit is indicated for use in the preparation and thawing of vitrified oocytes (Mll), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.
	Neither Ultra-Fast Vitri not Ultra-Fast Warm makes direct contact with the patient, only with the oocyte.	This product does not make direct contact with the patient, only with the gametes/embryos: Oocyte, PN through Blastocyst.
Embryo Stage	Ultra-Fast Vitri: Oocyte	Vitrification kit: Oocyte, PN through Blastocyst
	Ultra-Fast Warm: Oocyte	Thawing kit: Oocyte, PN through Blastocyst
Principle of Operation	Ultra-Fast Vitri: Provides users with the ability to cryopreserve supernumerary oocytes created during the in vitro fertilization procedure	Vitrification kit: Provides users with the ability to cryopreserve supernumerary oocytes or embryos created during the in vitro fertilization procedure
	Ultra-Fast Warm: Provides users with the ability to warm vitrified oocytes for use at a future point in time	Thawing kit: Provides users with the ability to warm vitrified oocytes or embryos for use at a future point in time
Vitrification Formulation	In a Medium 199 HEPES buffered Medium	In a Medium 199 HEPES buffered Medium
	Ethylene glycol	Ethylene glycol
	DMSO	DMSO
	Trehalose	Trehalose
	Hydroxypropyl Cellulose (HPC)	Hydroxypropyl Cellulose (HPC)
	Gentamicin	Gentamicin
Vitrification Protocol	Procedures provided for both Repro and Standard plates. Faster overall procedure with fewer steps.	Procedure provided for Repro plate. More steps and time to the procedure.
Vitrification Steps	2 Procedures, each procedure with 2 Steps. The first step consists of 1 min equilibration in ES. The second step consists of 1 min vitrification in VS.	2 Steps. The first step consists of a 15-minute equilibration involving BS and ES. The second step consists of 1-1.5 min vitrification involving VS.

<table>
<tr><th>Feature</th><th>Subject Device: Ultra-Fast Vitri and Ultra-Fast Warm</th><th>Predicate: Vitrification Kit and Thawing Kit (K171748)</th></tr>
<tr><td></td><td>The difference between the procedure using repro plates vs standard dishes relates to the volumes used (procedure on standard dish uses drops, this dish does not have wells) and the plate/dish in which the procedure is carried out.</td><td></td></tr>
<tr><td>Vitrification Media Component</td><td>Ultra-Fast Vitri devices can be composed on the following based on the reference number:<table><tr><td>VT601USUF (91268)</td><td>1×1.5mL vial ES
3×1.5mL vial VS</td></tr><tr><td>VT601USUF-4 (91269)</td><td>1×4mL vial ES
3×4mL vial VS</td></tr><tr><td>VT601USUF-ESx4 (91260)</td><td>4×1.5mL vial ES</td></tr><tr><td>VT601USUF-VSx4 (91261)</td><td>4×1.5mL vial VS</td></tr><tr><td>VT601USUF-ES4x4 (91266)</td><td>4×4mL vial ES</td></tr><tr><td>VT601USUF-VS4x4 (91267)</td><td>4×4mL vial VS</td></tr></table></td><td>Basic Solution (BS) 1.5mL x 1 Vial, Equilibration Solution (ES) 1.5mL x 1 Vial, and Vitrification Solution (VS) 1.5mL x 2 Vials</td></tr>
<tr><td rowspan="4">Thawing Formulation</td><td>In a Medium 199 HEPES buffered Medium</td><td>In a Medium 199 HEPES buffered Medium</td></tr>
<tr><td>Hydroxypropyl Cellulose (HPC) (v/v)</td><td>Hydroxypropyl Cellulose (HPC) (v/v)</td></tr>
<tr><td>Gentamicin</td><td>Gentamicin</td></tr>
<tr><td>Trehalose</td><td>Trehalose</td></tr>
<tr><td>Thawing Protocol</td><td>Faster overall procedure with fewer steps.</td><td>More steps and time to the procedure.</td></tr>
<tr><td>Thawing Steps</td><td>1 Step consisting of placing the oocyte 1 min in TS.</td><td>Multiple Steps involving three different solutions (TS, DS and WS).</td></tr>
<tr><td>Thawing Media Component</td><td>TS solution 4.0mL x 4 Vials</td><td>Thawing Solution (TS)4.0mL x 2 Vials
Diluent Solution (DS) 4.0mL x 1 Vial
Washing Solution (WS)4.0mLx1 Vial</td></tr>
<tr><td>Packaging</td><td>Solutions are packed in plastic vials. 4 vials are packed in a cardboard box.</td><td>Solutions are packed in plastic vials. 4 vials are packed in a cardboard box.</td></tr>
<tr><td>Sterile</td><td>Solutions sterilized using aseptic processing techniques through filtration. Vial containers are sterilized via radiation</td><td>Solutions sterilized using aseptic processing techniques through filtration Vial containers are sterilized via radiation</td></tr>
<tr><td>Endotoxin</td><td>Endotoxin by LAL methodology <0.25 EU/mL (LAL)</td><td>Endotoxin by LAL methodology <0.25 EU/mL (LAL)</td></tr>
<tr><td>Mouse Embryo Assay</td><td>>80% one-cell 96 hours</td><td>>80% one-cell 96 hours</td></tr>
<tr><td>Sterility Testing</td><td>Passes USP <71></td><td>Passes USP <71></td></tr>
<tr><td>pH Test</td><td>7.20 – 7.60</td><td>7.20 – 7.60</td></tr>
<tr><td>Biocompatibility</td><td>Passes</td><td>Passes</td></tr>
</table>

Feature	Subject Device: Ultra-Fast Vitri and Ultra-Fast Warm	Predicate: Vitrification Kit and Thawing Kit (K171748)
Storage	2 – 8°C	2 – 8°C
Shelf Life	12 months	12 months

9. Non-Clinical Performance Data

Bench testing included the following:

- Color/Appearance
- pH Testing
- Endotoxin testing
- Osmolality Testing
- Sterility Testing
- Gentamicin Test
- Initial Media Dispensing Validation

To demonstrate safety and effectiveness of Ultra-Fast Vitri and Ultra-Fast Warm and to show substantial equivalence to the predicate device, the Mouse Embryo Assay (MEA) was conducted using the subject device with revised protocols to align with the ultra-fast procedures. The Ultra-Fast Vitri and Ultra-Fast Warm passed the testing in accordance with FDA guidance shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- Mouse Embryo Assay (MEA) – Passed
    - *Mouse Embryo Assay for Assisted Reproduction Technology Devices,* issued January 5, 2021

10. Clinical Performance Data

Clinical performance data to support the safety and performance of the subject device was included in this submission. The referenced literature used Kitazato's vitrification and warming solutions (K171748 and K160864) and compared the effectiveness of vitrification and warming using the conventional protocol to the ultra-fast protocols of the subject device (i.e., vitrification: 1 minute in equilibration solution and 1 minutes in vitrification solutions; thawing: 1 minute in thawing solution at 37˚C). The study was conducted using 1,077 mature oocytes (n=519 for the conventional vitrification and warming protocols and n=558 for the ultra-fast protocols). The results from the study showed that oocyte survival rate after vitrification and thawing (100.0% vs. 90.9%), clinical pregnancy rate (65.2% vs. 54.3%), and live birth rate (56.5% vs. 52.2%) obtained with the ultra-fast vitrification and warming and with the conventional vitrification and warming protocols, respectively, were comparable.

11. Statement of Substantial Equivalence

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.