April 27, 2026

Kitazato Corporation
% Belén Fos Guarinos
Regulatory Affairs Director
Biomedical Supply S.l. Dba Dibimed
3 Jorge Comín Bajo 1-2
Valencia, 46015
SPAIN

Re: K260248
Trade/Device Name: Ultra-Fast Warm
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media And Supplements
Regulatory Class: II
Product Code: MQL
Dated: January 27, 2026
Received: January 27, 2026

Dear Belén Fos Guarinos:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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
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)*
K260248

Device Name
Ultra-Fast Warm

Indications for Use *(Describe)*
Ultra-Fast Warm is indicated for warming of previously vitrified oocytes (MII) 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

K260248

1. Submitter Information

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Ms. Kyoko Izumi
Quality Assurance Manager
Phone Number: (81) 545 65 7122

2. Correspondent Information

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Email: regulatory@dibimed.com
Contact: Belén Fos Guarinos
Title: Regulatory Affairs Director

3. Date of Preparation

April 27, 2026

4. Subject Device Information

Device Trade Name:	Ultra-Fast Warm
Common Name:	Warming medium for vitrified oocytes and blastocysts
Classification Name:	Reproductive media and supplements
Regulation Number(s):	884.6180
Product Code(s):	MQL, Reproductive Media and Supplements
Class:	Class II

5. Predicate Device Information

Device Trade Name: Ultra-Fast Vitri; Ultra-Fast Warm
Submission Number: K251305
Manufacturer: Kitazato Corporation

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

6. Device Description

Ultra-Fast Warm is a warming solution intended for the warming of previously vitrified oocytes (MII) and blastocyst stage embryos for use in Assisted Reproductive Technologies (ART) procedures.

Ultra-Fast Warm consists of a single media (TS; Thawing Solution) used for warming and removing cryoprotectants from vitrified oocytes and blastocyst stage embryos. The product is provided in four pre-packaged 4.0 mL vials.

TS in Ultra-Fast Warm contains Gentamicin. The medium in it undergoes sterilization via aseptic filtration, while the vials and storage devices are sterilized by radiation.

7. Indications for Use

Ultra-Fast Warm is indicated for warming of previously vitrified oocytes (MII) and blastocyst stage embryos.

8. Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Devices

The table below compares the intended use and technological characteristics of the subject and predicate device.

Feature	Subject Device: Ultra-Fast Warm	Predicate: Ultra-Fast Warm (K251305)	Comparison
Device Classification	Class II Media, Reproductive	Class II Media, Reproductive	Same
Product Code	MQL	MQL	Same
Regulation No.	21 CFR 884.6180	21 CFR 884.6180	Same
Manufacturer	Kitazato Corporation	Kitazato Corporation	Same
Intended Use	Reproductive media and supplements	Reproductive media and supplements	Same
Indications for Use	Ultra-Fast Warm is indicated for warming of previously vitrified oocytes (MII) and blastocyst stage embryos.	Ultra-Fast Warm is indicated for use in the preparation and warming of vitrified oocytes (MII).	***Similar***
Patient contact	This product does not come into direct contact with the patient; intended for use only with gametes and/or embryos.	This product does not come into direct contact with the patient; intended for use only with gametes and/or embryos.	Same
Gamete and/or Embryo stage	MII oocytes and blastocyst stage embryos	MII oocytes	***Similar***

Feature	Subject Device: Ultra-Fast Warm	Predicate: Ultra-Fast Warm (K251305)	Comparison
Applicable Population	The product is used for fertility treatment of humans	The product is used for fertility treatment of humans	Same
Principle of operation	Provides users with the ability to warm vitrified MII oocytes or blastocyst stage embryos for use at a future point in time.	Provides users with the ability to warm vitrified MII oocytes for use at a future point in time.	***Similar***
Thawing Formulation	In a Medium 199 HEPES buffered Medium	In a Medium 199 HEPES buffered Medium	Same
	Hydroxypropyl Cellulose (HPC) (v/v)	Hydroxypropyl Cellulose (HPC) (v/v)	Same
	Gentamicin	Gentamicin	Same
	Trehalose	Trehalose	Same
Thawing Steps	1 Step consisting of placing the oocyte/ blastocyst stage embryos 1 min in TS.	1 Step consisting of placing the oocyte 1 min in TS.	***Similar***
Thawing Media Component	TS solution 4.0mL x 4 Vials	TS solution 4.0mL x 4 Vials	Same
Packaging	Solutions are packed in plastic vials. 4 vials are packed in a cardboard box.	Solutions are packed in plastic vials. 4 vials are packed in a cardboard box.	Same
Sterile	Solutions sterilized using aseptic processing techniques through filtration. Vial containers are sterilized via radiation	Solutions sterilized using aseptic processing techniques through filtration Vial containers are sterilized via radiation	Same
Endotoxin	Endotoxin by LAL methodology <0.25 EU/mL (LAL)	Endotoxin by LAL methodology <0.25 EU/mL (LAL)	Same
Mouse Embryo Assay	>80% one-cell 96 hours	>80% one-cell 96 hours	Same
Sterility Testing	Passes USP <71>	Passes USP <71>	Same
pH Test	7.20 – 7.60	7.20 – 7.60	Same
Biocompatibility	Passes	Passes	Same
Storage	2 – 8°C	2 – 8°C	Same
Shelf Life	12 months	12 months	Same

The subject device and predicate device (Ultra-Fast Warm component) have identical technological characteristics. The differences are the indications for use, gamete and/or embryo stage, principle of operation, and thawing steps. The subject device and predicate device have the same intended use. These differences do not raise different questions of safety and effectiveness.

9. Non-Clinical Performance Data

Non-clinical performance testing was leveraged from the predicate device (K251305) to support the performance of the subject device.

10. Clinical Performance Data

The subject device, Ultra-Fast Warm, has expanded the intended use of the predicate device to include ultrafast warming of vitrified blastocysts, which included corresponding updates to the Instructions for Use and labeling. Supportive clinical evidence was provided to support this expanded intended use.

A retrospective clinical study by Yelke et al. (2025) evaluated outcomes of previously vitrified blastocyst stage embryos warmed using Ultra-Fast Warm compared to a conventional multi-step warming protocol. The study was conducted using 3,167 vitrified blastocyst warming cycles (1,461 blastocysts in the multi-step control group and 1,750 blastocysts in the one-step treatment group, with a subset of 1,886 PGT-A tested euploid blastocysts: 817 multi-step and 1,069 one-step). The results from the cohort study showed that post-warming survival rates (99.73% one-step vs. 99.59% multi-step), clinical pregnancy rate (72.1% one-step vs. 67.2% multi-step), and live birth rate (63.7% one-step vs. 57.0% multi-step) were comparable between the ultrafast warming (e.g., one-step) and traditional (e.g., multi-step) protocols. The results demonstrated comparable clinical and neonatal outcomes between the groups and did not identify new or different questions of safety or effectiveness associated with the use of Ultra-Fast Warm.

11. Conclusion

The results of the testing described above demonstrate that the Ultra-Fast Warm is as safe and effective as the predicate device and supports a determination of substantial equivalence.