August 7, 2024

Vitrolife Sweden AB
Nina Arvidsson
Official Applicant
Gustaf Werners gata 2
Vastra Frolunda, 42132
SWEDEN

Re: K240605
Trade/Device Name: Ultra RapidWarm™ Blast
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Received: July 9, 2024

Dear Nina Arvidsson:

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)*
K240605

Device Name
Ultra RapidWarm™ Blast

Indications for Use *(Describe)*
Ultra RapidWarm™ Blast is indicated for warming of vitrified human 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 – K240605

1. Submitter Information

Submitted by:
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2. Date Prepared: August 6, 2024

3. Device Identification

Trade Name:	Ultra RapidWarm™ Blast
Common Name:	Warming medium for vitrified blastocysts
Regulatory Class:	Class II
Regulation Number:	21 CFR 884.6180
Regulation Name:	Reproductive media and supplements
Product Code:	MQL (Media, Reproductive)

4. Predicate Device: RapidWarm™ Blast (K101003) manufactured by Vitrolife Sweden AB

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

5. Device Description
Ultra RapidWarm Blast is intended for warming vitrified human blastocyst stage embryos. The device consists of a single solution composed of a MOPS buffered solution containing gentamicin, human serum albumin (HSA) and sucrose.

The medium is aseptically filtered into gamma sterilized 5 mL PETG bottles with HDPE closures and a tamper evident seal. The medium can be used for up to 14 days after bottle opening.

6. Indications for Use
Ultra RapidWarm™ Blast is indicated for warming of vitrified human blastocyst stage embryos.

7. Comparison of intended use and technological characteristics of the subject and predicate devices

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

	Subject Device (K240605)	**Predicate Device (K101003)**	**Comparison**
Trade Name	Ultra RapidWarm Blast	RapidWarm Blast	N/A
Indications for Use	Ultra RapidWarm™ Blast is indicated for warming of vitrified human blastocyst stage embryos.	RapidWarm™ Blast is indicated for warming of vitrified human blastocyst stage embryos.	Same
Warming procedure	Ultra Warm Blast (250 mM sucrose): 2 minutes	Warm 1 Blast (250 mM sucrose): 2 minutes Warm 2 Blast (125 mM sucrose): 3 minutes Warm 3 Blast: 5–10 minutes	**Different:** The warming procesure of the subject and predicate devices are not the same. Differences in warming procedure do not raise different questions of safety and effectiveness (S&E).
Packaging	5 mL PETG bottle with HDPE closure	10 mL PETG bottle with HDPE closure	**Different:** The packaging of the subject and predicate devices are not the same. Differences in device packgaing do not raise different questions of S&E.
Storage conditions	Store dark at +2 to +8 °C	Store dark at +2 to +8°C	Same
pH	7.30 ± 0.10	7.30 ± 0.10	Same
Osmolality (mOsm/kg)	547 ± 20	528 ± 20 / 394±12 / 261±5	**Different:** The osmolality of the subject and predicate devices are not the same. Differences in osmolality do not raise different questions of S&E.
Bacterial endotoxins (LAL assay)	< 0.5 EU/mL	< 0.5 EU/mL	Same

Mouse Embryo Assay (MEA)	One-cell system: ≥80% embryos developed to expanded blastocyst at 96 hours after 2 minutes of exposure	One-cell: ≥ 70% re-expanded blastocyst 24 hours post-test	**Different:** The MEA specification of the subject and predicate devices are not the same. This difference does not raise a different question of S&E.
Sterilization method	Aseptic filtration	Aseptic filtration	Same
Shelf-Life	9 weeks 14 days (open bottle)	24 weeks	**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.

The subject and predicate device have the same indications for use and intended use. The subject and predicate device have different technological characteristics, including differences in warming procedure, specifications, and shelf-life. The different technological characteristics do not raise different questions of safety and effectiveness.

8. Summary of Non-Clinical Performance Testing
The following studies have been performed to support substantial equivalence to the predicate device:

- Aseptic filtration and filling validation testing that met the requirements of ISO 13408-1:2008/Amd1:2013 and ISO 13408-2:2018.
- Shelf-life testing was conducted to support a 9-week shelf-life for the subject device through demonstration that the product specifications (shown below) were met at time 0 and after real-time aging. Testing was also included on aged samples demonstrating that medium in bottles can maintain their specifications after 14 days of simulated use conditioning after bottle opening. Testing conducted is shown below:
  - Sterility testing per USP <71> (acceptance criterion: no microbial growth)
  - Bacterial endotoxins testing per USP <85> (acceptance criterion: <0.5 EU/ml)
  - pH measurements per USP <791> (acceptance criterion: 7.30±0.10)
  - Osmolality per USP <785> (acceptance criterion: 547±20 mOsm/kg)
  - Mouse embryo assay - One-cell system: ≥80% embryos developed to expanded blastocyst at 96 hours after 2 minutes of exposure.
- Transportation testing was conducted according to ASTM D4169-22 (DC-13) and cap/seal leak testing according to USP <1207.2>.

9. Summary of Clinical Performance Testing
A clinical evidence summary providing information to support the safety and performance of the subject device was included in this submission. The evaluation covers literature review and data from a study on a single step warming protocol identical to the subject device. The literature review summarized research

conducted with single-step warming versus multi-step standard warming procedures, and the results showed comparable embryo survival rate, clinical pregnancy rate, implantation rate, and live birth rate between blastocysts warmed with the single-step and multi-step warming procedures, indicating that a single-step warming procedure is equivalent to multi-step warming procedures. The clinical study used the Warm 1 Blast (K101003) as a surrogate for the subject device and compared the effectiveness of warming using a simplified warming protocol (2 minutes of warming in Warm 1 Blast) compared to standard warming protocol using RapidWarm Blast (K101003). The study was conducted in a university-based IVF center in France. A prospective pilot study with 86 cycles (52 blastocysts in the control group and 42 blastocysts in the treatment group) was conducted, followed by a cohort study including 868 cycles (578 blastocysts in the control group and 336 blastocysts in the treatment group). The results from the cohort study showed that embryo survival rate after warming (97.8% vs. 97.6%), clinical pregnancy rate (38.2% vs. 39.2%), and live birth rate (28.3% vs. 29.6%) obtained with the single-step warming and with the conventional standard warming protocol, respectively, were comparable.

9. 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.