September 12, 2025

FUJIFILM Irvine Scientific
Cindy Kha
Regulatory Affairs Specialist II
2511 Daimler Street
Santa Ana, California 92705

Re: K250445
Trade/Device Name: Fast Warm - NX
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media And Supplements
Regulatory Class: Class II
Product Code: MQL
Dated: February 14, 2025
Received: August 14, 2025

Dear Cindy Kha:

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,
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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.

Submission Number *(if known)*

K250445

Device Name

Fast Warm - NX

Indications for Use *(Describe)*

Fast Warm - NX is intended for use in assisted reproductive procedures for the thawing 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.

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510(k) SUMMARY – K250445

Submitter Information:

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Contact Person:

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Email: cindy.kha@nexpringhealth.com

Date Prepared: September 11, 2025

Device Identification:

Trade Name:	Fast Warm – NX
Common Name:	Warming medium for vitrified blastocysts
Regulation Name:	Reproductive Media and Supplements
Regulation Number:	21 CFR 884.6180
Regulatory Class:	Class II
Product Code:	MQL (Media, Reproductive)

Predicate Device:

Vit Kit – Warm NX (K190152)
FUJIFILM Irvine Scientific, Inc.

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

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Device Description:

Fast Warm – NX is a dual-buffered solution (HEPES & MOPS) of Continuous Single Culture Medium (CSCM) containing gentamicin sulfate, 20% (v/v) dextran serum supplement (DSS), and 1.0M trehalose. DSS is a protein supplement consisting of 50 mg/mL human serum albumin (HSA) and 20 mg/mL dextran. DSS is used at 20% (v/v) in Fast Warm – NX for a final concentration of 10 mg/mL HSA and 4 mg/mL dextran. The product is supplied as a ready to use liquid in two (2) different configurations, a kit containing multiple vials of either two (2) x 20mL or six (6) x 2mL. The medium can be used for up to 14 days after bottle opening. The device specifications are outlined in the comparison table below.

Intended Use:

Fast Warm – NX is intended for use in assisted reproductive procedures for the thawing of vitrified human blastocyst stage embryos.

Comparison of intended use and technological characteristics of the subject and predicate devices:

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

	Subject Device (K250445)	**Predicate Device (K190152)**	**Comparison**
Trade Name	Fast Warm – NX	Vit Kit – Warm NX	N/A
Indications for Use	Fast Warm – NX is intended for use in assisted reproductive procedures for the thawing of vitrified human 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 through day 3 cleavage stage embryos and blastocyst stage embryos.	The indications for use statements subject and predicate devices are not identical; however, they have the same intended use (i.e., warming of embryos).

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Embryo Stage	Blastocysts	MII oocytes, pronuclear zygotes through blastocysts	**Different:** The stages of embryos for the subject and predicate devices are not the same. Differences in embryo stages do not raise different questions of safety and effectiveness (S&E).
Formulation	CSCM, Trehalose, Dextran, HSA, Gentamicin, Sodium Bicarbonate, HEPES, MOPS	CSCM, Trehalose, Dextran, HSA, Gentamicin, Sodium Bicarbonate, HEPES, MOPS	Same
Warming procedure	Fast Warm – NX: 1 minutes	TS: 1 minute DS: 4 minutes WS: 8 minutes	**Different:** The warming procedure of the subject and predicate devices are not the same. Differences in warming procedure do not raise different questions of S&E.
Packaging	2 mL PPCO bottle with PPCO closure; 20 mL PETG bottle with HDPE closure	2 mL PPCO bottle with PPCO closure; 20 mL PETG bottle with HDPE closure	Same
Storage conditions	2 – 8 °C	2 – 8 °C	Same
pH	7.05 – 7.45	7.05 – 7.45	Same
Osmolality (mOsm/kg)	775 – 950, [after] 1:1 dilution	1,550 – 1,900	Similar
Bacterial endotoxins (LAL assay)	≤ 0.6 EU/mL	≤ 0.6 EU/mL	Same

Fast Warm – NX

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Mouse Embryo Assay (MEA)	One-cell system: ≥80% embryos developed to expanded blastocyst at 96 hours after one minute of exposure	One-Cell: ≥ 80% expanded blastocyst after 96 hours	**Different:** The MEA specification of the subject and predicate devices are not the same. This difference does not raise different questions of S&E.
Sterilization method	Aseptic filtration	Aseptic filtration	Same
Shelf-Life	6 months 14 days (open bottle)	6 months	**Different:** The subject device has a 14-day use-life after opening, while the predicate device does not. Differences in use-life do not raise different questions of S&E.

The subject and predicate device have similar indications for use statements and the same intended use – warming of vitrified blastocysts. 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.

Summary of Non-Clinical Testing:

The following studies have been performed to support substantial equivalence to the predicate device:

- Aseptic filtration and filling validation that met the requirements of ISO 13408-1:2008/Amd1:2013 and ISO 13408-2:2018. For filter challenge testing per ISO 13408-2, the surrogate solution used for testing did not contain antimicrobials.

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- 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 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 per USP<71> and 21 CFR § 610.12
  - Endotoxin per USP<85>
  - Mouse Embryo Assay (MEA)
  - pH per USP<791>
  - Osmolality per USP<785>
  - Appearance

- Transportation testing was conducted according to ASTM D4169-22 (DC-13) and cap/seal leak testing

Summary of Clinical Performance Testing

Clinical performance data to support the safety and performance of the subject device for fast warming of vitrified blastocysts was included in this submission. The referenced literature used FUJIFILM Irvine Scientific's warming solution (K190152, identical to the subject device) and compared the effectiveness of blastocyst warming using the standard multiple-step protocol to the single-step warming protocol (i.e., 1 minute in thawing solution at 37˚C) of the subject device. The study was conducted using 752 frozen blastocysts (n=376 for the standard multiple-step warming protocol and n=376 for the single-step warming protocol). The results showed that blastocyst survival rate after warming (100.0% vs. 100%), clinical pregnancy rate (54.0% vs. 52.7%), and live birth rate (44.4% vs. 43.1%) obtained with the single-step warming and with the standard multiple-step warming protocols, respectively, were comparable.

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.