June 21, 2019

FUJIFILM Irvine Scientific, Inc.
Jayme Yamaguchi-Owens
Regulatory Affairs Manager
2511 Daimler Street
Santa Ana, CA 92705

Re: K190152
Trade/Device Name: Vit Kit- Freeze NX and Vit Kit- Warm NX
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: May 17, 2019
Received: May 20, 2019

Dear Jayme Yamaguchi-Owens:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For
Sharon M. Andrews
Assistant Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190152

Device Name
Vit Kit - Freeze NX
Vit Kit - Warm NX

Indications for Use *(Describe)*
Vit Kit - Freeze NX (Vitrification Freeze Kit) is intended for use in the vitrification of oocytes (MII) and pronuclear (PN) zygotes through day 3 cleavage stage embryos and 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.

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

K190152

I. General Information on Submitter

Submitted/Address: FUJIFILM, Irvine Scientific, Inc.
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Telephone: 800-437-5706
Facsimile: 949-261-6522

Contact Person: Jayme Yamaguchi-Owens
FUJIFILM Irvine Scientific, Inc.
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Santa Ana, CA 92705
Telephone: 800-437-5706
Facsimile: 949-261-6522
Email: see below
Jayme.yamaguchi-owens@fujifilm.com

II. Date Prepared:

June 20, 2019

III. General Information

Device Name: Vit Kit - Freeze NX
Vit Kit - Warm NX

Common Name: Vitrification Cryopreservation Media and Warming Kit

Regulatory Class: Class II

Regulation Number: 21 CFR 884.6180

Regulation Name: Reproductive Media and Supplements

Product Code: MQL (Media, Reproductive)

IV. Predicate Device:

Vit Kit – Freeze, Vit Kit – Thaw
K160006, Irvine Scientific

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

V. Description of the Device:

The five media products that comprise the two kits, Vit Kit – Freeze NX and Vit Kit – Warm NX, consist of a basal media of Continuous Single Culture Medium (CSCM) which utilizes MOPS, HEPES and sodium bicarbonate buffers, 20% (v/v) DSS, 10μg/mL gentamicin and varying levels of cryoprotectants, including dimethyl sulfoxide (DMSO), trehalose, and ethylene glycol (EG).

The two freeze media in the Vit Kit – Freeze NX are intended to be used sequentially for the preparation and cryopreservation of oocytes (MII) and pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

The three media in the Vit Kit - Warm NX are intended for sequential use in the thawing and recovery of cryopreserved oocytes (MII) and pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

VI. Indications for Use:

Vit Kit - Freeze NX (Vitrification Freeze Kit) is intended for use in the vitrification of oocytes (MII) and pronuclear (PN) zygotes through day 3 cleavage stage embryos and 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.

VII. Predicate Device Comparison

The table below shows a comparison of the intended use and technological characteristics of the subject device and predicate device.

Table 1: Comparison of Characteristics

Characteristic	Subject Device K190152 Vit Kit – Freeze NX Vit Kit – Warm NX	Predicate Device K160006 Vit Kit – Freeze Vit Kit - Thaw	Comparison
Indications for Use	Vit Kit - Freeze NX (Vitrification Freeze Kit) is intended for use in the vitrification of oocytes (MII) and pronuclear (PN) zygotes through day 3 cleavage stage embryos and 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.	Vit Kit – Freeze (Vitrification Freeze Kit) is intended for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos. Vit Kit – Thaw (Vitrification Thaw Kit) is intended for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.	There are minor differences in wording, but the intended uses are the same.
Components	Vitrification Media	Vitrification Media	Identical

Characteristic	Subject Device K190152 Vit Kit – Freeze NX Vit Kit – Warm NX	Predicate Device K160006 Vit Kit – Freeze Vit Kit - Thaw	Comparison
	Thawing Media	Thawing Media	
Media Components			
Vitrification Media	CSCM EG (7.5, 15%) DMSO (7.5, 15%) Trehalose (0.5M) DSS HSA Gentamicin Sodium Bicarbonate HEPES MOPS	Medium 199 EG (7.5, 15%) DMSO (7.5, 15%) Sucrose (0.5M) DSS HSA Gentamicin Sodium Bicarbonate HEPES	The predicate and subject device formulations are similar. The predicate device uses sucrose instead of trehalose and it uses a HEPES buffer instead of a dual zwitterionic buffer.
Thawing Formulation	CSCM Trehalose (0.5M, 1.0M) Dextran HSA Gentamicin Sodium Bicarbonate HEPES	Medium 199 Sucrose (0.5M, 1.0M) Dextran HSA Gentamicin Sodium Bicarbonate HEPES	The predicate and subject device formulations are similar. The predicate device uses sucrose instead of trehalose and it uses a HEPES buffer instead of a dual zwitterionic buffer.

Vit Kit - Freeze NX
Vit Kit - Warm NX

Characteristic	Subject Device K190152 Vit Kit – Freeze NX Vit Kit – Warm NX	Predicate Device K160006 Vit Kit – Freeze Vit Kit - Thaw	Comparison
	MOPS		
Endotoxin	≤ 0.6 EU/mL	≤ 0.6 EU/mL	Identical
MEA	≥ 80% expanded blastocyst after 96 hours in culture	≥ 80% expanded blastocyst after 96 hours in culture	Identical
pH	ES: 7.05 – 7.44 VS: 7.05 – 7.44 TS: 7.05 – 7.45 DS: 7.05-7.45 WS: 7.05 – 7.45	ES: 7.05 – 7.54 VS: 7.05 – 7.54 TS: 7.05-7.44 DS: 7.05-7.44 WS: 7.05–7.44	The predicate and subject device specifications are similar.
Osmolality ($mOsm/KgH_2O$)	ES: 1,150 – 1,1550 VS: 1,220-1,620 TS: 1,550-1,900 DS: 830,-930 WS: 265-300	ES: 1,055-1,445 VS: 1,100-1,588 TS: 1,732-1,912 DS: 857-910 WS: 268-292	The osmolality specifications are similar.
Sterilization Method	Aseptic Filtration	Aseptic Filtration	Identical

As shown in the table above, the intended use of the subject and predicate device is the same. The technological characteristics of the subject and predicate device are different - the subject device formulation utilizes trehalose instead of sucrose, has a different basal medium formulation, and different osmolality and pH specifications. However, different types of safety and effectiveness questions are not raised by these differences in technological characteristics.

Vit Kit - Freeze NX
Vit Kit - Warm NX

Non-clinical Performance Data:

Vit Kit - Freeze NX and Vit Kit – Warm NX media were tested for the following performance characteristics at baseline and following accelerated aging (per ASTM F1980-16):

- Appearance
- pH (per USP <791>)
- Osmolality (per USP <785>)
- Endotoxin (per USP <85>)
- Sterility (per USP <71>)
- Mouse Embryo Assay

The following additional assessments were performed on the subject device:

- Simulated Distribution and Handling per ASTM D4169-16

The subject device passed the predefined acceptance criteria for these tests.

VIII. Conclusion:

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