September 26, 2024

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

Re: K241341
Trade/Device Name: cryo-GO Vitrification Device
Regulation Number: 21 CFR 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: II
Product Code: MQK
Received: August 30, 2024

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,

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.

Submission Number *(if known)*

K241341

Device Name

cryo-GO Vitrification Device

Indications for Use *(Describe)*

cryo-GO Vitrification Device is a cryopreservation device intended for use in vitrification procedures to contain and maintain human oocytes (MII), 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.

510(k) SUMMARY

Submitter/Address	FUJIFILM Irvine Scientific, Inc. 2511 Daimler Street Santa Ana, CA 92705 Telephone: (949) 261-7800
Contact Person:	Cindy Kha FUJIFILM Irvine Scientific, Inc. 2511 Daimler Street Santa Ana, CA 92705 Telephone: (949) 261-7800 Email: cindy.kha@fujifilm.com
Date Prepared:	September 20, 2024
Trade Name:	cryo-GO Vitrification Device
Common Name:	Cryopreservation Storage Device
Regulation Name:	Assisted Reproduction Labware
Regulation Number:	21 CFR 884.6160
Regulatory Class:	Class II
Product Code:	MQK (Labware, Assisted Reproduction)
Legally Marketed Predicate Device:	VitriGuard (K200815) ORIGIO A/S /CooperSurgical, Inc. 95 Corporate Drive, Trumbull, CT 06611 The predicate device has not been subject to a design-related recall.

Device Description:

The cryo-GO Vitrification Device is a sterile, single-use, closed assisted reproduction storage device for use in vitrification procedures to contain and maintain oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

The cryo-GO Vitrification Device is composed of an injection molded body with an extended loading tip (4.45 inches long with a 0.65 inch loading tip), an injection molded cap (1.76 inches), and a total device combined length of 5.05 inches. Visible marks are on the distal loading tip, body, and at the opening of the cap, to indicate the location of the tip, the upright orientation of the device and the opening of the cap, respectively. The body and cap include a taper design that create a seal when assembled prior to plunging the device in liquid nitrogen for vitrification and for subsequent storage. The device is provided in five different colors: red, yellow, green, blue, and purple. The subject devices are radiation sterilized to a sterilization assurance level of 10^{-6} and have a one-year shelf-life.

Indication for Use:

cryo-GO Vitrification Device is a cryopreservation device intended for use in vitrification procedures to contain and maintain human oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

Comparison of Intended Use and Technological Characteristics with the Predicate Device:

The table below includes a comparison of the intended use and technological characteristics of the subject and predicate devices.

	Subject Device cryo-GO Vitrification Device K241341	**Predicate Device VitriGuard K200815**	**Comparison**
Indications for Use	cryo-GO Vitrification Device is a cryopreservation device intended for use in vitrification procedures to contain and maintain human oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and	VitriGuard is intended for use as a cryopreservation storage device in vitrification procedures and indicated to contain and maintain human oocytes (MII), 4-8 cell embryos and blastocyst stage embryos.	The subject and predicate device have differences in their indications for use statements, as the predicate device is not intended for vitrification of pronuclear (PN) zygotes. The addition of zygotes does not represent a new intended use as both devices have the same

	blastocyst stage embryos.		intended use (i.e., to serve as a cryopreservation storage device for use in vitrification procedures).
Design	Stick (injection molded body) with cap	Stick with cap	**Same**
Materials	Methyl Methacrylate Butandiene Styrene (MBS) with pad printed ink areas (tip marking and end cap marking)	Polystyrene with black marker bands	**Different:** The subject and predicate devices are made of different materials. This difference in device materials does not raise different questions of safety and effectiveness (S&E).
Vitrification System	Closed	Closed	**Same**
Cooling Rate	-1,650°C/ min	-2,271°C/min	**Different:** The cooling rate of the subject device is lower than the predicate device. This difference in cooling rate does not raise different questions of S&E.
Warming Rate	+16,500°C/ min	+36,377°C/min	**Different:** The warming rate of the subject device is lower than the predicate device. This difference in cooling rate does not raise different questions of S&E.
Endotoxin (EU/mL)	≤ 2 EU/ device	≤ 2 EU/ device	**Same**
Mouse Embryo Assay (MEA)	≥ 80% expanded blastocyst within 96 hours	≥ 80% embryos developed to expanded blastocyst at 96h	**Same**
Single-Use	Yes	Yes	**Same**
Shelf Life	1 year	Unknown	**Different:** Differences in shelf-life between the subject and predicate device do not raise different questions of S&E.
Sterile	Radiation, Sterility Assurance Level (SAL) 10^{-6}	Radiation, Sterility Assurance Level (SAL) 10^{-6}	**Same**

As shown in the table above, there are differences in the subject and predicate device indications for use statements; however, they have the same intended use. The subject and predicate devices also have differences in technological characteristics, including cooling/warming rate, materials, and shelf-life. These technological differences do not raise different questions of safety and effectiveness.

Non-Clinical Performance Data

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

Sterilization Testing:

Radiation sterilization and validation was conducted in accordance with ISO 11137-1:2018, 11137-2:2015, and the 2024 FDA guidance *Submission and Review of Sterility Information in Premarket Notification (510(k) Submissions for Devices Labeled as Sterile*. The subject devices have a Sterility Assurance Level (SAL) of 10^{-6}.

Simulated Transportation/Package Integrity:

Simulated transportation and package integrity testing was performed after accelerated aging to the end of the stated one-year shelf-life per ASTM F1980-21. The simulated transportation and package integrity assessments conducted are shown below:

- Simulated transportation conditioning per ASTM D4169-22
- Visual inspection of packaging
- Dye penetration testing per ASTM F1929-23
- Seal strength (peel) testing per ASTM F88/F88M-21

The testing above demonstrated that devices can withstand the rigors of shipping and maintain the sterile barrier over the stated shelf-life duration.

Shelf Life:

The following tests were completed and demonstrated that the subject devices maintained their performance in newly manufactured devices and after one year of accelerated aging per ASTM F1980-21:

- Cooling/warming rate testing
- Dimensional testing
- Durability testing following exposure to liquid nitrogen (cracks, deformation, discoloration or other damage)
- Seal integrity/leakage testing following exposure to liquid nitrogen
- Capping and de-capping force testing
- Ink marker resistance testing
- Endotoxin Test: ≤ 2 EU/ device according to USP<85>, <161>
- Mouse Embryo Assay: ≥ 80% expanded blastocyst within 96 hours in accordance with the 2021 FDA guidance, *Mouse Embryo Assay for Assisted Reproduction Technology Devices*.

Summary:

The results of the performance testing described above demonstrate that the cryo-GO Vitrification Device is as safe and effective as the predicate device and supports the determination of substantial equivalence.