December 14, 2017

Kitazato Corporation
% Diane Sudduth
Senior Consultant, RA
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, TX 78746

Re: K171748
Trade/Device Name: Vitrification Kit and Thawing Kit
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL, MQK
Dated: November 9, 2017
Received: November 13, 2017

Dear Diane Sudduth:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171748

Device Name
Vitrification Kit and Thawing Kit

Indications for Use *(Describe)*
The Vitrification Kit is indicated for use in the preparation, vitrification and storage of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos.
The Thawing Kit is indicated for use in the preparation and thawing of vitrified 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.

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510(k) Summary

Vitrification Kit and Thawing Kit

K171748

1. Submission Sponsor

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2. Submission Correspondent

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3. Date Prepared

14 December 2017

4. Device Identification

Trade/Proprietary Name:	Vitrification Kit and Thawing Kit
Common/Usual Name:	Vitrification Cryopreservation Media
Classification Name:	Reproductive Media and Supplements
Classification Number:	884.6180

Product Code:	MQL – Media, Reproductive
	MQK – Labware, Assisted Reproduction
Device Class:	Class II
Classification Panel:	Obstetrics/Gynecology

5. Legally Marketed Predicate Devices

K160006, Vit Kit® - Vitrification Freeze Kit/ Vitrification Thaw Kit, Irvine Scientific Sales Co., Inc.

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

6. Device Description

The Vitrification and Thawing Kits are composed of a set of six media to vitrify and warm MII oocytes, and pronuclear (PN) zygotes through blastocyst stage embryos for Assisted Reproductive Technology (ART) procedures.

The Vitrification Kit includes three media components, Basic Solution (BS), Equilibration Solution (ES) and Vitrification Solution (VS), containing the cryoprotectants ethylene glycol, trehalose, and dimethyl sulfoxide. During the vitrification process, embryos are first exposed to ES and then to VS. In the case of the oocytes, use BS and ES. Using this methodology, the permeating cryoprotectants can replace water in the oocyte, PN through blastocyst stage embryos prior to vitrification and storage in liquid nitrogen. The Vitrification Kit comes prepackaged with one 1.5 ml vial of BS and ES, two 1.5 ml vials of VS, 4 Cryotop devices (Cryotop CL, Cryotop SC, or Cryotop US), and 2 Repro Plates.

The Thawing Kit is composed of three media used stepwise for thawing and removing cryoprotectants from vitrified oocytes, and PN through blastocyst stage embryos. The Thawing Kit is composed of TS (Thawing Solution), DS (Dilution Solution) and WS (Wash Solution). The Thawing Kit comes pre-packaged with two 4.0 ml vials of thawing solution, one 4.0 ml vial of dilution solution, one 4.0 ml vial of washing solution, one Repro Plate, and two 35 mm dishes.

All the media in the Vitrification Kit and Thawing Kit contain Gentamicin. The media in these kits undergo aseptic filtration, while storage devices and plates are sterilized by radiation. The specifications for the Vitrification Kit and Thawing Kit are listed in Table 1 below.

7. Indication for Use Statement

The Vitrification Kit is indicated for use in the preparation, vitrification and storage of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos.

The Thawing Kit is indicated for use in the preparation and thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos.

8. Substantial Equivalence Discussion

The following table compares the Vitrification Kit and Thawing Kit to the predicate devices with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. As noted in the table, there are differences in indications for use and technological characteristics between the subject and predicate devices; however, the differences indications for use do not represent a new intended use, and differences in the technological characteristics do not raise any different questions of safety or effectiveness as compared to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	**Kitazato Corporation**	**Irvine Scientific Sales Co., Inc.**
Trade Name	**Vitrification Kit and Thawing Kit**	**Vitrification Freeze Kit and Vitrification Thaw Kit (Vit-Kit®-Thaw)**
510(k) Number	Not assigned	K160006
Product Code	MQL, MQK	MQL
Regulation Number	884.6180	884.6180
Regulation Name	Reproductive Media and Supplements	Reproductive Media and Supplements
Indications for Use	The Vitrification Kit is indicated for use in the preparation, vitrification and storage of oocytes (MII), pronuclear(PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos. The Thawing Kit is indicated for use in the preparation and thawing of vitrified oocytes (MII), 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 oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.
Components of Kit	Vitrification Media Thawing Media	Vitrification Freeze Kit Vitrification Thaw Kit
Embryo Stage	Oocyte, PN through Blastocyst	Oocyte, PN through Blastocyst

Manufacturer	**Kitazato Corporation**	**Irvine Scientific Sales Co., Inc.**
Trade Name	**Vitrification Kit and Thawing Kit**	**Vitrification Freeze Kit and Vitrification Thaw Kit (Vit-Kit®-Thaw)**
Principal of Operation	Provides users with the ability to cryopreserve supernumerary oocytes or embryos created during the in vitro fertilization procedure and then to re-warm them for use at a future point in time	Provides users with the ability to cryopreserve supernumerary oocytes or embryos created during the in vitro fertilization procedure and then to re-warm them for use at a future point in time
Vitrification Formulation	In a Medium 199 HEPES buffered Medium	In a Medium 199 HEPES buffered Medium
	Ethylene glycol	Ethylene glycol
	DMSO	DMSO
	Trehalose	Sucrose
	Hydroxypropyl Cellulose (HPC)	Dextran Serum Supplement (DSS)
	Gentamicin	Gentamicin
Vitrification Steps	2 Step	2 step
Thawing Formulation	In a Medium 199 HEPES buffered Medium	In a Medium 199 HEPES buffered Medium
	Hydroxypropyl Cellulose (HPC) (v/v)	Dextran Serum Supplement (DSS) (v/v)
	Gentamicin	Gentamicin
	Trehalose	Sucrose
Thawing Steps	3 Step	3 Step
Carton Packaging	Each solution is contained in plastic vials. Vials are packed in a card board outer box with partition.	Each solution is contained in plastic vials. Vials are packed in a card board outer box with partition.
Cryopreservation Storage Device Used With	Kitazato Corporation Cryotop®CL-K112695 Cryotop®SC - K140072 Cryotop®US– K153027	Irvine Scientific HSV Straw – K092398 CryoTip – K041562
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

Manufacturer	**Kitazato Corporation**	**Irvine Scientific Sales Co., Inc.**
Trade Name	**Vitrification Kit and Thawing Kit**	**Vitrification Freeze Kit and Vitrification Thaw Kit (Vit-Kit®-Thaw)**
Endotoxin	Endotoxin by LAL methodology <0.25 EU/mL(LAL) for Media	Endotoxin by LAL methodology <0.25EU/mL)
Mouse Embryo Assay	>80% development to blastocyst at 96 hours	>80% one-cell 96 hours
Sterility Testing	Passes	Passes
pH Test	7.20 – 7.60	Not available
Biocompatibility	Passes	Passes
Storage	2 – 8°C	2 – 8°C
Shelf Life	1 year	1 year

9. Non-Clinical Performance Data

The subject device is identical to the Kitazato Cryotop Vitrification and Thawing Kit cleared under K160864. Design verification tests were performed on the identical device cleared under K160864. Testing included sterilization validation, packaging validation, and performance (bench) testing. The device passed all the testing. Therefore, the information provided in K160864 was leveraged in this submission to support substantial equivalence of the Vitrification Kit and Thawing Kit.

10. Clinical Performance Data

The clinical information presented provides published papers that specifically identify vitrification/thawing media with HPC that are similar to or identical to the predicate device and the use of the Cryotop as the vitrification method for the cryopreservation of oocytes and blastocyst from human and mouse. A summary of the results are shown below:

- Literature 1: results of the study show comparable oocyte survival rate, implantation rate, clinical pregnancy rate, and live birth rate between a surrogate device (with similar formulation and cryoprotectants to the subject device) and vitrification media containing serum substitute supplement[1]

[1] A combination of hydroxypropyl cellulose and trehalose as supplementation for vitrification of human oocytes: a retrospective cohort study (Coello et al, Journal of Assisted Reproduction Genetics, 2016 March; 33(3): 413-421)

- Literature 2: results of the study show that human blastocyst survival rate following vitrification was comparable between a surrogate device (with similar formulation to the predicate device) and vitrification media containing serum substitute supplement[2]
- Literature 3: results of the study show comparable oocyte survival rate to other methods of vitrification and a fertilization rate and quality blastocyst rate as comparable to fresh oocytes. [3]

Birth rates following use of vitrified oocytes as compared to the vitrification methods used in the predicate device were shown to be comparable. Each of the studies reported survival rates of oocytes and embryos that are consistent with normal ART procedures using similar IVF treatments and cryopreservation techniques.

11. Statement of Substantial Equivalence

The results of the performance testing described above demonstrate that the Vitrification Kit and Thawing Kit are as safe and effective as the predicate device and supports a determination of substantial equivalence.

[2] Hydroxypropyl cellulose as an option for supplementation of cryoprotectant solutions for embryo vitrification in human assisted reproductive technologies (Mori et al, Reproductive BioMedicine Online, 2015 June;30(6):613-21)

[3] Efficiency of a Closed Vitrification System with Oocytes and Blastocysts (Inoue et al, Low Temp Med, 2014; 40(3): 53-59)