August 17, 2020

Kitazato Corporation
% Michael A. Siano, MA
Regulatory Affairs Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, TX 78746

Re: K192845
Trade/Device Name: Sperm Freeze, Sperm Fridge
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: July 6, 2020
Received: July 9, 2020

Dear Michael A. Siano:

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,

Monica D. Garcia, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192845

Device Name
Sperm Freeze
Sperm Fridge

Indications for Use *(Describe)*
Sperm Freeze is intended for the cryopreservation of human semen samples prior to use in assisted reproductive technology procedures.

Sperm Fridge is intended to protect human semen samples during refrigerated storage prior to use in assisted reproductive technology procedures.

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

K192845 - Sperm Freeze, Sperm Fridge

1. Submitter Information

Applicant: Kitazato Corporation
Contact: Mr. Futoshi Inoue
President and Representative Director
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2. Correspondent Information

Contact: Michael A. Siano
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USA
Phone: (512) 327-9997

3. Date Prepared: August 17, 2020

4. Device Information

Device Name: Sperm Freeze, Sperm Fridge
Common Name: Cryopreservation/refrigeration media
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Product Code: MQL (Media, Reproductive)
Regulatory Class: Class II

5. Predicate Device(s)

Device Name: Freezing Medium TEST Yolk Buffer (TYB) with Glycerol, Refrigeration Medium TEST Yolk Buffer (TYB)
510(k) Number: K991421
Manufacturer: Irvine Scientific

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

6. Device Description

Sperm Freeze and Sperm Fridge are preservation media intended for preserving sperm (short-term and long-term) for in vitro fertilization (IVF) and assisted reproduction technologies (ART). There are two methods for sperm preservation; freezing and refrigeration. Freezing is necessary for long-term sperm preservation, but may have disadvantages such as reduced survival rate and/or sperm motility after thawing. Refrigeration makes it possible to preserve sperm for several days without freezing and may be preferable for short-term preservation. Both products are intended to be used exclusively in a laboratory environment by trained professionals.

Sperm Freeze is a is a Tris-buffered solution containing the cryoprotectants glycerol and trehalose that is used for long-term sperm cryopreservation procedures. Sperm Fridge is a buffered solution (TES and Tris) that includes a nutrient source for sperm (dextrose) that is used for short-term sperm preservation procedures. Sperm Freeze and Sperm Fridge are offered in two volumes (0.5 mL and 10 mL, and 0.5 mL is sold in a pack of 5).

Device specifications for Sperm Freeze and Sperm Fridge are detailed in Tables 1 and 2 below.

7. Indications for Use

Sperm Freeze is intended for the cryopreservation of human semen samples prior to use in assisted reproductive technology procedures.

Sperm Fridge is intended to protect human semen samples during refrigerated storage prior to use in assisted reproductive technology procedures.

8. Substantial Equivalence Discussion

A detailed comparison of the intended use and technological features of the subject and predicate device are described in the tables below:

Table 1: Comparison of Characteristics, Sperm Fridge

Attribute	**K191485** **Subject Device:** **Sperm Fridge**	**K991421** **Predicate Device:** **Refrigeration Medium- TEST Yolk Buffer (TYB)**	**Comparison**
Manufacturer	Kitazato	Irvine Scientific	Different
Product Code	MQL	MQL	Same
Indications for use	Sperm Fridge is intended to protect human semen samples during refrigerated storage prior to use in assisted reproductive technology procedures.	Refrigeration Medium -Test Yolk Buffer and Freezing Medium - Test Yolk Buffer with Glycerol are intended for use in assisted reproductive technology procedures that involve the manipulation and storage of semen samples prior to use in in vitro fertilization and other similar treatments. Refrigeration Medium - Test Yolk Buffer is specifically designed for to protect semen samples during refrigerated storage, while Freezing	Different

		Medium - Test Yolk Buffer with Glycerol is intended to be used as a cryopreservative of semen samples.	
Rx/OTC	Rx	Rx	Same
Ingredients	TES; Tris; Dextrose; Gentamicin Sulfate; Recombinant Human Albumin	TES; Tris; Dextrose; Egg Yolk; Penicillin-G; Streptomycin Sulfate	Different
pH	7.2–7.6	7.2 ± 0.2	Different
Endotoxin	≤ 0.25 EU/mL	≤ 3 EU/mL	Different
Sterility	No growth	No growth	Same
Sperm Fridge-survival	≥ 80% (45 min)	N/A	Different
Storage Conditions	–20°C	–10°C	Different
Shelf-life	1 year	2 years	Different
Sterilization	Aseptic Filtration	Aseptic Filtration	Same

Table 2: Comparison of Characteristics, Sperm Freeze

Attribute	**K191485 Subject Device: Sperm Freeze**	**K991421 Predicate Device: Freezing Medium-TEST Yolk Buffer(TYB) with Glycerol**	**Comparison**
Manufacturer	Kitazato	Irvine Scientific	Different
Product Code	MQL	MQL	Same
Indications for Use	Sperm Freeze is intended for the cryopreservation of human semen samples prior to use in assisted reproductive technology procedures.	Refrigeration Medium -Test Yolk Buffer and Freezing Medium - Test Yolk Buffer with Glycerol are intended for use in assisted reproductive technology procedures that involve the manipulation and storage of semen samples prior to use in in vitro fertilization and other similar treatments. Refrigeration Medium - Test Yolk Buffer is specifically designed for to protect semen samples during refrigerated storage, while Freezing Medium - Test Yolk Buffer with Glycerol is intended to be used as a cryopreservative of semen samples.	Different
Rx/OTC	Rx	Rx	Same
Ingredients	Water; Calcium DL-Lactate; Disodium Hydrogenphosphate; Gentamicin; Glycerol; Glycine; Lauryl Alcohol; Magnesium Sulfate; Potassium Chloride; Recombinant Human Albumin;	Water; TES; Tris; Sodium Citrate; Fructose; Glycerol; Egg Yolk; Penicillin-G; Streptomycin Sulfate	Different

	Sodium Bicarbonate; Sodium Chloride; Sodium Phosphate; Tocopherol; Trehalose; Tris		
pH	7.2–7.6	7.0-7.4	Different
Endotoxin	≤ 0.25 EU/mL	≤ 3 EU/mL	Different
Sterility	No growth	No growth	Same
Sperm Cryo-survival	≥ 80% (45 min)	N/A	Different
Storage Conditions	–20 °C	–10 °C	Different
Shelf-Life	1 year	2 years	Different
Sterilization	Aseptic Filtration	Aseptic Filtration	Same

The subject and predicate device have similar indications for use statements and have the same intended use - to cryopreserve or refrigerate human semen samples prior to use in assisted reproductive technology procedures. The subject and predicate device have different technological characteristics, including differences in formulation, pH, endotoxin, storage conditions, and shelf-life. These differences do not raise different questions of safety and effectiveness as compared to the predicate device.

9. Summary of Non-Clinical Performance Testing

To demonstrate safety and effectiveness of Sperm Freeze and Sperm Fridge and to show substantial equivalence to the predicate device, Kitazato completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the devices are met.

The device passed all testing in accordance with internal requirements, national standards, and international standards shown below:

- Appearance
- Endotoxin per USP <85>
- Osmolality
- pH per USP <791>
- Sperm cryo-survival
- Sperm refrigeration survival
- Sterility per USP <71>

Shelf-life performance testing was conducted at Time 0 and beyond the shelf-life (>12 months) to ensure that the product specifications listed above were met.

10. Conclusions

The results of the performance testing described above demonstrate that Sperm Freeze and Sperm Fridge are as safe and effective as the predicate device and supports a determination of substantial equivalence.