November 9, 2018

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

Re: K181469
Trade/Device Name: Cryotop®US-flash and Cryotop®US-scoop
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: II
Product Code: MQK
Dated: October 10, 2018
Received: October 11, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Michael T. Bailey -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181469

Device Name
Cryotop®US-flash and Cryotop®US-scoop

Indications for Use *(Describe)*

Cryotop®US-flash and Cryotop®US-scoop are cryopreservation storage devices that are intended for use in vitrification procedures to contain and maintain human oocytes (MII) and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K181469

1. Submission Sponsor

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2. Submission Correspondent

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Contact: Diane Sudduth
Title: Senior Consultant, RA

3. Date Prepared

November 8, 2018

4. Device Identification

Trade Name:	Cryotop®US-flash and Cryotop®US-scoop
Common Name:	Cryopreservation Storage Device
Regulation Name:	Assisted Reproduction Labware
Regulation Number:	21 CFR 884.6160
Product Code:	MQK (Labware, Assisted Reproduction)
Regulatory Class:	II

5. Predicate Device

Cryotop®US (K153027) manufactured by Kitazato Corporation (formally KITAZATO BIOPHARMA CO., LTD.) This predicate device has not been subject to any design related recalls.

6. Device Description

This 510(k) covers two subject devices, the Cryotop®US-flash and Cryotop®US-scoop that are modified versions of the predicate device (Cryotop®US, K153027). Both devices are cryopreservation storage devices intended for embryo/oocyte vitrification. Cryotop®US-flash and Cryotop®US-scoop are provided sterile and are for single-use only.

The Cryotop®US-flash is composed of a polypropylene straw and an acrylonitrile butadiene styrene handle with a polyethylene terephthalate fine tip where oocytes or embryos are loaded. The fine tip of this device is flat with a triangular-shaped area for oocyte/embryo loading. The Cryotop®US-scoop is composed of a polypropylene straw and a polystyrene handle and fine tip where oocytes or embryos are loaded. The fine tip of this device is U-shaped. After oocyte or embryo loading, the handle of the subject devices is inserted into the straw enclosure. A hermetic seal is created via a tapered handle with a stop location integrated into the handle. As the handle is placed into the straw enclosure it creates a closed system keeping the fine tip isolated from the liquid nitrogen. The straw component of both devices also includes a weight at its distal end to aid in maintaining correct device position during storage in liquid nitrogen.

7. Indication for Use

Cryotop®US-flash and Cryotop®US-scoop are cryopreservation storage devices that are intended for use in vitrification procedures to contain and maintain human oocytes (MII) and embryos.

8. Substantial Equivalence Discussion

Devices	K181469 (subject device)	K153027 (predicate device)
Indications for Use	Cryotop®US-flash and Cryotop®US-scoop are cryopreservation storage devices that are intended for use in vitrification procedures to contain and maintain human oocytes (MII) and embryos.	The Cryotop®US is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human 4-8 cell and blastocyst stage embryos.
Fundamental design	Same as the predicate	A handle incorporating a sample-loading tip, and a cap (straw) to close the device.
Film tip shape	Cryotop®US-flash – Flat Cryotop®US-scoop – U-shape	Flat
Dimensions	Cryotop®US-flash: • Total length – 116 mm • Film tip length – 18 mm • Handle length – 98 mm • Straw length – 90 mm • Straw diameter – 3 mm Cryotop®US-scoop: • Total length – 113 mm • Film tip length – 15 mm • Handle length – 98 mm • Straw length – 90 mm • Straw diameter – 3 mm	• Total length – 105 mm • Film tip length – 20 mm • Handle length – 85 mm • Straw length – 100 mm • Straw diameter – 2.9 mm
Mode of action	Same as the predicate	Vitrification method – The loaded, closed device is placed in liquid nitrogen
Cooling rate	Same as the predicate	3000°C/min
Warming rate	Same as the predicate	44000°C/min
Materials	Cryotop®US-flash: • Handle – acrylonitrile butadiene styrene • Fine tip – polyethylene terephthalate • Straw – polypropylene/stainless steel Cryotop®US-scoop: • Handle and fine tip – polystyrene • Straw - polypropylene/stainless steel	• Handle – acrylonitrile butadiene styrene Film sheet – polyethylene terephthalate • Straw – polypropylene/stainless steel

The subject devices are indicated to contain, vitrify and maintain MII oocytes and all stages of embryo development (2 PN-blastocyst stage), whereas the predicate device is only indicated for cleavage and blastocyst stage embryos. Inclusion of MII oocytes and earlier stage embryos (2 PN) in the subject devices indications does not represent a new intended use because processing of the embryos or oocytes is applicable to same patient population with same clinical needs – infertility treatment or fertility preservation. Therefore, the subject and predicate devices have the same intended use.

Cryotop®US-flash and the predicate device have the same technological characteristics including design, mode of action, materials and cooling/warming rates; however, they have differences in dimensions. Cryotop®US-scoop and the predicate device have the same fundamental design, mode of action and cooling/warming rates; however, they have differences in dimensions and materials. The differences noted do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Data

Non-clinical performance testing was conducted to support substantial equivalence to the predicate device. Cryotop®US-flash and Cryotop®US-scoop passed all the tests shown below in accordance with internal requirements and applicable standards.

- Cooling Rate Testing – 3,000°C/min
- Warming Rate Testing – 44,000°C/min
- Dimensional Testing – Outer diameter and length per specifications
- Durability Testing: No burst or liquid nitrogen ingress into straw after 30 second immersion
- Mechanical Tensile Testing – Tensile strength to withstand 5N
- Bacterial Endotoxins – <0.5 EU/device per USP <85> and ANSI/AAMI ST72:2002/(R)2010
- Mouse Embryo Assay (MEA) – ≥80% of 1-cell embryos developed to blastocysts at 96 hours
- Transportation simulation testing per ASTM D4169-09
- Shelf-life Testing:
  - Package integrity testing:
    - Dye penetration test per ASTM F1929-15
    - Seal strength test per ASTM F88/F88M-15
  - Dimensional analysis, mechanical, durability, endotoxin, and MEA testing in accordance with the methods and acceptance criteria mentioned above

In addition, information regarding sterilization validation per ISO 11137-1:2006 and ISO 11137-2:2013 provided in K153027 was leveraged to support substantial equivalence.

10. Clinical Performance Data

Clinical information provided in K171748 (Kitazato Corporation Vitrification Kit and Thawing Kit) that incorporates the predicate Cryotop®US device was leveraged in supporting the additional uses of the Cryotop®US-flash and Cryotop®US-scoop for oocyte an 2 PN embryo vitrification procedures.

11. Conclusion

The subject and predicate devices have the same intended use and comparable technological characteristics. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject devices are substantially equivalent to the predicate device.