



Food and Drug Administration
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March 14, 2016

KITAZATO BioPharma Co., Ltd.
% Richard A. Vincins, CBA, CQA, RAC (US,EU)
Vice President, Quality Assurance
Emergo Global Consulting, LLC
816 Congress Avenue, Suite 1400
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Re: K153027
Trade/Device Name: Cryotop® US
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: II
Product Code: MQK
Dated: February 9, 2016
Received: February 12, 2016

Dear Richard A. Vincins,

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Herbert P. Lerner -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

Indications for Use

510(k) Number (if known)

K153027

Device Name

Cryotop®US

Indications for Use (Describe)

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.

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

Cryotop®US

K153027

1. Submission Sponsor

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3. Date Prepared

March 9, 2016

4. Device Identification

Trade/Proprietary Name: Cryotop®US

Common/Usual Name: Cryopreservation Storage Device

Classification Name: Assisted Reproduction Labware

Regulation Number: 884.6160

Product Code: MQK
Device Class: Class II
Classification Panel: Obstetrics/Gynecology

5. Legally Marketed Predicate Device

K122982, CRYOLOCK™, BioTech Inc.

6. Device Description

CryotopUS 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. As part of the vitrification procedure, the cells to be stored are loaded on the tip of the CryotopUS device for subsequent storage.

The CryotopUS device is composed of an acrylonitrile butadiene styrene (ABS) handle shaft with a polyethylene terephthalate (PET) film tip and a polypropylene straw enclosure. The fine tip has a flat film area for loading embryos. The CryotopUS device has a “straw” enclosure system for when the unit is placed in the liquid nitrogen. The handle shaft is designed with a “stop” for inserting the film tip/shaft handle into the straw enclosure. A hermetic seal is created via a tapered shaft handle with a stop location integrated into the handle. As the handle is placed into the straw enclosure this creates a closed system keeping the film tip isolated from the liquid nitrogen. The straw enclosure system has a weight at the distal end to place the straw and the shaft inside in a correct position in the liquid nitrogen. The CryotopUS device is provided sterile and is for single use only. The CryotopUS device has been designed to maintain the integrity of the human embryos through the freezing and thawing process.

7. Indication for Use Statement

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.

8. Substantial Equivalence Discussion

The following **Table 1** compares the CryotopUS to the predicate device 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.

Table 1– Comparison of Characteristics

Manufacturer	Kitazato BioPharma Co., Ltd.	BioTech Inc.	Significant Differences
Trade Name	Cryotop®US	CRYOLOCK™	
510(k) Number	Not assigned	K122982	
Product Code	MQK	MQK	Same
Regulation Number	884.6160	884.6160	Same
Regulation Name	Assisted Reproduction Labware	Assisted Reproduction Labware	Same
Indications for Use	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	The CRYOLOCK™ is a cryopreservation storage device that is intended for use in Vitrification procedures to contain and maintain human 1-cell stage embryos	Similar; the indications for use are both for the vitrification and storage of human embryos.
Mechanism of Action	Vitrification Method	Vitrification Method	Same
Technology Overview	The CryotopUS is designed to contain, freeze and maintain embryos. The device consists of a two piece assembly comprised of the main part containing the fine tip film area and the “straw.” The handle shaft and straw are designed to be closed system. The straw is weighted to allow proper alignment in the storage container. The CryotopUS device is packaged in a single barrier sterilization pouch.	The Cryolock is designed to contain, freeze and maintain embryos. The device is a square shape stick with four flat surfaces. The device is composed of two piece assembly with the main part for the embryo placement and the handle shaft and cap designed to be a closed system. The CryoLock device is packaged in a single barrier sterilization pouch.	Same

Manufacturer	Kitazato BioPharma Co., Ltd.	BioTech Inc.	Significant Differences
Trade Name	Cryotop®US	CRYOLOCK™	
Material Composition	PET, ABS, Polypropylene	PET, Polypropylene	Similar; both devices are made of medical grade plastics that are commonly used.
Sterile	Radiation, SAL 10 ⁻⁶	Radiation, SAL 10 ⁻⁶	Same
Single-Use	Yes	Yes	Same
Shelf Life	3 years	3 years	Same
Cooling Rate	3,000°C/min	1,494°C/min	Different; though the cooling rate is different, non-clinical performance testing from both devices support intended use.
Rewarming Rate	44,000°C/min	21,000°C/min	Different; though the warming rate is different, non-clinical performance testing from both devices support intended use.
Contact with Warming Medium	The tip (film) and the shaft of CryotopUS are taken out from the straw. Directly immerse the tip (film) into thawing solution	The tip (film) and the shaft of Cryolock are taken out from the body. Directly immerse the tip (film) into thawing solution.	Same
Performance Testing	Passed	Passed	Same
Mouse Embryo Testing	Passed	Passed	Same
Sterility Validation Testing	Passed	Passed	Same

The technological characteristics of the CryotopUS are comparable to the predicate device. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

9. Non-Clinical Performance Data

As part of demonstrating substantial equivalence to the predicate device, Kitazato BioPharma completed a number of non-clinical performance tests. The CryotopUS device meets all the requirements for overall design, sterilization, and performance testing results, confirming that the design output meets the design inputs and specifications for the device.

The CryotopUS device passed all the testing in accordance with internal requirements and applicable standards that is shown below to support substantial equivalence of the subject device:

- Cooling Rate Testing: Cooling rate of 3,000 °C/min passed
- Warming Rate Testing: Warming rate of 44,000 °C/min passed
- Dimensional Testing: Passes outer diameter and length according to specifications
- Durability Testing: No burst or liquid nitrogen inside the straw after 30 second immersion
- Mechanical Tensile Testing: Tensile strength to withstand 5N
- Endotoxin Testing: Endotoxin values conform to the value ≤ 0.5 EU/device
- Sterility Testing: No microbial growth from sterility testing
- Mouse Embryo Assay: $\geq 80\%$ of 1-cell control embryos develop at 96 hours
- Shelf life testing
- Package integrity testing

Note: The performance testing, Mouse Embryo Assay (MEA), and sterility test are all performed on samples from routine manufactured lots; a Certificate of Analysis is provided with each lot of CryotopUS device.

10. Conclusion

The results of the testing described above provide reasonable assurance that the CryotopUS is as safe and effective as the predicate device and supports a determination of substantial equivalence.