DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 14, 2016

Reprolife Inc.
% Diane Sudduth
Sr. Consultant, RA/QA
Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701

Re: K162051
Trade/Device Name: Cryotec
Regulation Number: 21 CFR 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: Class II
Product Code: MQK
Dated: November 11, 2016
Received: November 14, 2016

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.

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,

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)*

K162051

Device Name
Cryotec

Indications for Use *(Describe)*

This device is a vitrification storage device that is intended for use in vitrification procedures to contain and maintain human 4-8 cell or 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

for

CRYOTEC

K162051

1. Submission Sponsor

REPROLIFE Inc.
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Contact: Koichi Takeda, Director, Global Certification Division

2. Submission Correspondent

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Email: project.management@emergogroup.com

3. Date Prepared

12/12/2016

4. Device Identification

Trade/Proprietary Name:	Cryotec
Common/Usual Name:	Cryopreservation storage device
Classification Regulation:	884.6160
Classification Name:	Assisted Reproduction Labware
Product Code:	MQK (Labware, Assisted Reproduction)
Device Class:	Class II
Classification Panel:	Obstetrics and Gynecology

5. Legally Marketed Predicate Device(s)

Kitazato, CryotopUS, K153027. The predicate device has not been subject to a design-related recall.

6. Device Description

Cryotec is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human 4-8 cell or blastocyst stage embryos. It is designed to enable physicians and embryologists to preserve and to store vitrified embryos for assisted reproduction technology procedures.

The Cryotec device is composed of a two piece assembly with a polyethylene terephthalate (PET) film sheet attached to a PET handle, and a weighted polyvinylchloride cap to cover the film sheet during handling and storage. During vitrification procedures, the film sheet is loaded with embryos, capped, and immersed in liquid nitrogen. The capped design creates a hermetic seal, resulting in a closed system keeping the film sheet and embryos isolated from liquid nitrogen. The cap is weighted to allow proper alignment in the storage container. The Cryotec device is provided sterile and is for single use only. The Cryotec device has been designed to maintain the integrity of the human embryos through the freezing and thawing process.

The specifications for the Cryotec are as follows:

Appearance:	Particle free, no cracks
Durability:	No breakage, no liquid nitrogen inside the cap
Tensile Strength:	≥ 5N
Endotoxin:	< 0.5 EU/device
Sterility:	No growth
MEA (1-cell):	≥ 80% blastocyst

7. Indication for Use Statement

This device is a vitrification storage device that is intended for use in vitrification procedures to contain and maintain human 4-8 cell or blastocyst stage embryos.

8. Substantial Equivalence Discussion

The following table compares the Cryotec to the predicate device (Cryotop®US) with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Comparison of Characteristics

Manufacturer	**KITAZATO BioPharma Co.,**	**REPROLIFE Inc.**	**Comparison**
Trade Name	Cryotop®US	Cryotec	
510(k) Number	K153027	K162051	-
Product Code	MQK	MQK	-
Regulation Number	884.6160	884.6160	-
Regulation Name	Assisted Reproduction	Assisted Reproduction Labware	-
Indications for Use:	The 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.	This device is a vitrification storage device that is intended for use in vitrification procedures to contain and maintain human 4-8 cell or blastocyst stage embryos.	Same

Overall Design	The device consists of a two piece assembly comprised of the main part containing the fine tip film area and the "straw." The straw is designed to be sealed. The straw is weighted to allow proper alignment in the storage container. The CryotopUS device is packaged in a single barrier sterilization pouch.	The device is a square shape stick with four flat surfaces. The device is composed of two piece assembly with the film for embryo placement and handle shaft and weighted cap designed to be a closed system. The Cryotec device is packaged in a single barrier sterilization pouch.	Similar
Material Composition	PET, ABS, Polypropylene	PET	Different
Sealing Mechanism	The shaft handle contains a taper and stop. When inserted into the straw, a hermetically sealed closed system is formed.	The shaft is inserted into straw to form a hermetic seal creating a closed system.	Same
Method of Action	Vitrification Method	Vitrification Method	Same
Sterilization method	Radiation, SAL 10^{-6}	Radiation, SAL 10^{-6}	Same
Cooling Rate	3,000°C/min	1500°C/min	Different
Rewarming Rate	44,000°C/min	42,000°C/min	Different
Rewarming method	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 Cryotec are taken out from the cap. Directly immerse the tip (film) into thawing solution	Same
Shelf life	3 years	2 years	Different
Mouse Embryo	≥80% blastocyst (1-cell)	≥80% blastocyst (1-cell)	Same
Endotoxin	0.5 EU/device	0.5 EU/device	Same

The subject and predicate device have the same intended use – vitrification and storage of 4-8 cell or blastocyst stage embryos.

The technological characteristics are different – the subject device has a different material composition, cooling rate, warming rate, and shelf life. However, different types of safety or effectiveness questions are not raised by these differences in technological characteristics. Non-clinical performance data has been provided to evaluate the effect of the different technological characteristics of the subject device.

9. Non-Clinical Performance Data

The Cryotec device conforms to product quality test specifications: appearance, dimension, durability, tensile strength, endotoxin and Mouse Embryo Assay. The Cryotec device has been evaluated for the cooling/warming rate, mechanically tested, sterility tested, and mouse embryo assay supporting that all the specifications have met the acceptance criteria for the device. The following testing has been performed to support substantial equivalence:

Performance Testing

- Cooling Rate Testing: Cooling rate of 1,500 °C/min.; met specifications
- Warming Rate Testing: Warming rate of 42,000 °C/min.; met specifications
- Visual Inspection: All devices are particle free with no cracks; met specifications
- Dimensional Testing: Passes outer diameter and length according to specifications

- Durability Testing: Following immersion into liquid nitrogen, no breakage of the stick or cap, no liquid nitrogen inside the cap; met specifications
- Mechanical Tensile Testing: Tensile strength to withstand 5N; met specifications
- Endotoxin Testing: Endotoxin values conform to the value < 0.5 EU/device; met specifications
- Sterility Testing: No microbial growth from sterility testing; met specifications
- Mouse Embryo Assay: ≥80% of 1-cell control embryos develop within 96 hours; met specifications
- 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 Cryotec device.

11. Statement of Substantial Equivalence

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