EPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

June 30, 2017

Reprobitech Corp.
Huai L. Feng, Ph.D.
Director
42-31 Colden Street, Suite 202
Flushing, NY 11355

Re: K162640
Trade/Device Name: iVitri® EZ
Regulation Number: 21 CFR 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: II
Product Code: MQK
Dated: June 2, 2017
Received: June 6, 2017

Dear Huai L. Feng:

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,

Benjamin R. Fisher -S

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)*
K162640

Device Name
iVitri® EZ

Indications for Use *(Describe)*
The iVitri® EZ 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
K162640 - iVitri® EZ

1. Submission Sponsor:

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Email: Reprobiotech@gmail.com

2. Contact Person:

Dr. Huai L. Feng
Reprobiotech Corp.
Director
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Flushing, NY 11355
Doctorf99@gmail.com
Tel: (516) 301-6171

3. Date Prepared: June 30, 2017

4. Device Information:

Name of Device	iVitri® EZ
Common Name	Cryopreservation Storage Device
Classification Name	Assisted Reproduction Labware
Regulation	21 CFR 884.6160
Product Code	MQK (Labware, Assisted Reproduction)
Device Class	II

5. Predicate Device Information:

BioTech, Inc. - CRYOLOCK™ (K122982)

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

6. Device Description:

The iVitri®EZ device 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 iVitri® EZ device is composed of a two-piece polystyrene assembly with a square-shaped stick (body) and cap. As part of the vitrification procedure, the embryos are loaded on the tip, and capped for subsequent storage following vitrification. The tip of the storage device is curved to aid in maintaining and securing the embryos during handling procedures. The stick and cap include a tapered design that creates a hermetic seal, forming a closed storage system. Markings on the stick and tip of the device are used to aid in the proper orientation during embryo loading procedures. The device is provided sterile and is for single use only.

Product specifications are listed in the table below:

Parameter	Specification
Cooling Rate	-3,020°C/min
Warming Rate	40,694 °C/min
Sterilization	Radiation, SAL 10^{-6}
Endotoxin	≤0.5 EU/device
MEA	1-Cell MEA ≥80% expanded blastocyst formation at 96 hours

7. Indication for Use:

The iVitri® EZ 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. Comparison of Intended Use and Technological Characteristics of Subject and Predicate Devices:

Parameter	iVitri EZ (K162640 – Subject Device)	CRYOLOCK (K122982 – Predicate Device)	Comments
Indication for Use	The iVitri® EZ 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 predicate device is only indicated for use for 1-cell stage embryos, the predicate and subject device have the same intended use – vitrification and storage of human embryos.
Design	Consists of a stick (body) component including an embryo loading area and a cap. The stick and cap are designed to be hermetically sealed (e.g., twisting cap and body together) to form a closed storage device.	Consists of a stick (body) component including an embryo loading area and a cap. The stick and cap are designed to be hermetically sealed (e.g., twisting cap and body together) to form a closed storage device.	Same
Materials	Polystyrene	Polystyrene	Same
Cooling/Warming Rate	Cooling: -3,020°C/min Warming: +40,694°C/min	Cooling: -1,494°C Warming: +21,000	Different: The cooling and warming rates are higher in the subject device than in the predicate device. These differences do not raise different questions of S&E as they are within the range of cooling and

			warming rates cleared for other devices with similar uses.
Sterilization Method/SAL	Radiation, SAL 10^{-6}	Radiation, SAL 10^{-6}	Same
MEA	1-Cell MEA: ≥80% expanded blastocyst formation at 96h	1-Cell MEA: ≥80% blastocyst formation at 96h	Same
Endotoxin	≤ 0.5 EU/device	≤ 2.0 EU/Device	Different – the endotoxin specification is higher for the predicate device. However, this does not raise a different S&E question

As noted in the table above, the devices have the same intended use and are technologically comparable. Differences in technological characteristics noted above do not raise different questions of safety or effectiveness.

9. Non-Clinical Characteristics Performance Data:

As part of demonstrating substantial equivalence to the predicate device, the following non-clinical performance tests were conducted. The iVitri® EZ passed all of the testing in accordance with internal requirements and applicable standards to support substantial equivalence of the subject device:

- Cooling/warming rate testing: The purpose of this testing was to evaluate the cooling and warming rates of the subject device. Temperature recording equipment was used to document the temperature profile of devices when used as prescribed in the Instructions for Use throughout the cooling and warming portions of the vitrification process. Results showed a cooling rate of -3,020°C/min, and a warming rate of 40,694 °C/min.
- Durability and closure integrity testing: The purpose of this testing was to assess the integrity of the device following exposure to liquid nitrogen. The samples were assembled as described in the Instructions for Use and submerged in liquid nitrogen. The samples were then exposed to 37°C temperatures. Samples were then assessed for signs of leakage, damage (breaks, cracks, etc.), deformation or discoloration. The acceptance criteria were that devices must not exhibit any of the failure modes described above. Test samples met the acceptance criteria.
- Endotoxin testing per USP<85>: ≤0.5 EU/device
- Mouse Embryo Assay (MEA): 1-Cell mouse embryos were incubated in extracts of the subject device at 37°C in an atmosphere containing 5% CO_2. The percent of embryos developed to the expanded blastocyst stage at 96 hours were assessed in comparison with the control group. The acceptance criterion was 1-Cell MEA: ≥80% expanded blastocyst formation at 96 hours.
- Sterilization validation per ISO 11137-1:2006(R)2011 and ISO 11137-2:2013.
- Package integrity testing following accelerated aging per ASTM F1980-16:
    - Dye penetration testing per ASTM F929-15
    - Seal strength testing per ASTM F88/F88M-15

- Shelf-life studies (real-time and accelerated) were conducted to ensure that the following product specifications were met:
    - MEA
    - Durability and closure integrity testing
    - Device appearance (discoloration, deformation, damage)
    - Dimensional assessments

10. Conclusion:

The results of the testing described above demonstrate that the iVitri® EZ device is as safe and effective as the predicate device and supports a determination of substantial equivalence.