DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 9, 2014

BioTech, Inc.
% Robyn Scopis
Regulatory Consultant
Regulatory Specialist, Inc.
3722 Avenue Sausalito
Irvine, CA 92606

Re: K122982
Trade/Device Name: CRYOLOCK™
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted reproduction labware
Regulatory Class: II
Product Code: MQK
Dated: December 26, 2013
Received: January 6, 2014

Dear Robyn Scopis,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K122982

Device Name
CRYOLOCK™

Indications for Use *(Describe)*
The CRYOLOCK™ is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human 1-cell 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Benjamin R. Fisher -S
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JAN - 9 2014

510(k) SUMMARY

510(k) Owner	BioTech Inc. 11539 Park Woods Circle Suite 202 Alpharetta, GA 30005 TEL: 678 947 8173 FAX: 678 947 5580
Contact person	Robyn Scopis Regulatory Consultant to BioTech, Inc. Regulatory Specialists, Inc. 3722 Ave. Sausalito Irvine, CA 92606 TEL: 949.422.3853 FAX: 949.552.2821 EMAIL: robyn@regulatoryspecialists.com
Date summary was prepared	December 9, 2014
Name of device	CRYOLOCK™
Common Name	Assisted Reproduction Devices
Classification Name	Assisted Reproduction Labware
Regulation	884.6160
Product Code	MQK
Predicate	HSV Straw K041562 Rapid-I K090832

Description

The CRYOLOCK™ is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human 1-cell stage embryos.

The CRYOLOCK™ cooling rate: -1,494°C/min at -60°C
The CRYOLOCK™ warming rate: +21,000°C /min

CRYOLOCK™ is a square shape stick, with 4 flat surfaces. Both the cap and body are produced from the same material (polystyrene medical grade). The cap and body possess the same coefficient of expansion, ensuring an equally secure coupling at room temperature as well as at low cryogenic temperatures facilitating an even temperature conduction from side to side of the device. Body and cap have gaps on their extremes that allow easy grip with forceps during handling.

Intended Use

CRYOLOCK™ is intended for use as an assisted reproduction labware.

Indications for Use

The CRYOLOCK™ is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human 1-cell stage embryos.

Technological Characteristics

The predicates and the CRYOLOCK™ were compared in the following areas and found to have similar technological characteristics and to be equivalent:

- Intended Use
- Principles of Use
- Fundamental Technology
- Biocompatibility
- Tip Marking
- Single Use
- Sterility Assurance Level (SAL)
- Endotoxin Test
- Mouse Embryo Assay (MEA)
- Loading Volume
- Survival Rate with One Cell Mouse Embryos
- Cleavage Rate
- Blastocyst Rate

The predicates and the CRYOLOCK™ were compared in the following areas and found to have minor different technological characteristics. The following differences have been determined to not have any impact on the safety or efficacy of the CRYOLOCK™:

- System Components
- Packaging
- Materials
- Dimensions
- Cap
- Cooling Rate
- Warming Rate
- Colors Available
- Loading Method
- Closure System
- Accessories

The following non-clinical performance tests were conducted:

VD Max Radiation Validation for CRYOLOCK™
One-cell mouse embryo development in extracted "embryo-tested" culture medium (5 test articles POOLED)
Endotoxin titer and interference screening using the Kinetic Turbidimetric method
MEM Elution
CRYOLOCK™ Vitrification Device Temperature Profiles Closed Protocols
Comparison of survival of mouse zygotes after vitrification using two closed systems
Accelerated Aging of Sterile Medical Device Packages for CRYOLOCK™ and its Associated Packaging
Container and Closure: Bacterial/Immersion Integrity Test Using Immersion, Pressure and Vacuum Final Report
Transportation and Distribution ASTM D4169-2009
Contamination Assessment of the Cryopreservation Device, the CRYOLOCK™
Container and Closure Integrity Test for CRYOLOCK™ Device Closed System Using Immersion in Contaminated Liquid Nitrogen
Dose Audit Summary Report for CRYOLOCK™
CRYOLOCK™ Package Integrity – Shelf Life Real Time Aging Protocol
Molding Process Validation
Liquid Nitrogen (LN) Penetration testing

Conclusions from non-clinical performance data

After performing non-clinical performance studies, the data shows that the CRYOLOCK™ is substantially equivalent to the predicates as an Assisted Reproduction Labware.