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

February 16, 2017

ORIGIO a/s
% Roaida Johnson
Director, RA New Product Development
CooperSurgical, Inc.
95 Corporate Drive
Trumbull, CT 06611

Re: K162833
Trade/Device Name: VitriGuard™
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: II
Product Code: MQK
Dated: January 17, 2017
Received: January 18, 2017

Dear Roaida Johnson:

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)*
K162833

Device Name
VitriGuard™

Indications for Use *(Describe)*
VitriGuard 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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CooperSurgical

510(k) Summary
K162833 - VitriGuard™
Cryopreservation Storage Device

Submission Sponsor Information

Company Name: ORIGIO a/s
Company Address: Knardrupvej 2
2760 Måløv
Denmark
Telephone: +45 46790200
Fax: +45 46790302

Submission Correspondent Information

Company Name: CooperSurgical Inc.
Company Address: 95 Corporate Drive
Trumbull, CT 06611
Telephone: 203-601-5200 (Ext. 3325)
Fax: 203-601-9870

Contact Person: Roaida Johnson
Date Prepared: February 15, 2017

Device Information

Trade Name:	VitriGuard™
Common Name:	Cryopreservation Storage Device
Device Class:	II
Classification Number:	21 CFR 884.6160
Classification Name:	Assisted Reproduction Labware
Product Code:	MQK (Labware, Assisted Reproduction)

Predicate Device Information

The CooperSurgical VitriGuard cryopreservation storage device is substantially equivalent to the following predicate:

Primary Predicate: CRYOLOCK™ cryopreservation storage device (K122982)

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

Device Description

VitriGuard 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 VitriGuard device is composed of a two-piece polystyrene assembly that includes a hexagonal shaped stick and cap. As part of the vitrification procedure, the embryos to be stored are loaded on the tip, also referred to as the leaf, and capped with a pre-cooled cap for subsequent storage following vitrification. The leaf has a trough area for loading, maintaining, and securing the embryos. The stick and cap include a taper design that creates a hermetic seal, forming a closed system. Markings at the end of the stick and the tip of the device provide visual aid for proper device orientation. The device is provided sterile and is for single use only. The VitriGuard has been designed as a cryopreservation storage device to maintain the integrity of human 4-8 cell and blastocyst stage embryos throughout the cooling, storage, and warming processes.

Product specifications are listed in the table below:

Parameter	Specification
Cooling rate	-2,271°C/min
Warming rate	36,377°C/min
Sterilization	Radiation, SAL 10^{-6}
Endotoxin	≤2.0 EU/device
MEA	≥80% blastocyst at 96 hours (1-cell)

Indications for Use

VitriGuard 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.

Substantial Equivalence Discussion

The substantial equivalence of the subject device to the predicate is discussed below in Table 1 in respect to: indications for use, principles of operation, technological characteristics, materials, and performance.

Table 1: Comparison of VitriGuard to the Predicate Device

Property	Subject Device VitriGuard™	Predicate CRYOLOCK™	Significant Differences
510(k) Number	K162833	K122982	N/A
Indications for Use	VitriGuard 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. Although 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.
Technology Overview	The device is designed to contain, vitrify and maintain human embryos. The device is composed of a two-piece assembly with the main stick containing a fine tip area, called the "leaf," and a cap. The handle shaft and cap are designed to be a hermetically sealed closed system.	The device is designed to contain, vitrify and maintain human embryos. The device is composed of a two-piece assembly with the main stick containing a fine tip area, called the "leaf," and a cap. The handle shaft and cap are designed to be a hermetically sealed closed system.	Same
Sterility	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}	Same
Sterilization Method	Radiation	Radiation	Same
Number of Uses	Single Use, Disposable	Single Use, Disposable	Same
Shelf Life	2 Years	3 Years	Different. The subject device has a shorter shelf life, which does not raise different questions of safety and effectiveness.
Material Composition	Polystyrene	Polystyrene	Same
Cooling Rate	-2,271°C/min	-1,494°C/min	Different. However, both devices have cooling rates that are typical for these types of devices, and do not raise different questions of safety and effectiveness.
Rewarming Rate	36,377°C/min	21,000°C/min	Different. However, both devices have warming rates that are typical for these types of devices, and do not raise different questions of safety and effectiveness.
Endotoxin Testing	≤2.0 EU/device	≤2.0 EU/device	Same
Mouse Embryo Testing	≥80% blastocyst at 96 hours (1-cell)	≥80% blastocyst at 96 hours (1-cell)	Same

Non-Clinical Performance Testing

As part of demonstrating substantial equivalence to the predicate device, the following non-clinical performance tests were conducted. The VitriGuard device meets all requirements for overall design, sterilization, and performance testing results, confirming that the design outputs meet the design inputs and specifications for the device.

The VitriGuard device passed all the testing in accordance with internal requirements and applicable standards to support substantial equivalence of the subject device:

- Gamma Sterilization Validation per ISO 11137-1:2006/(R)2010 and 11137-2:2013
- Shipping and Distribution Testing per ISTA 3A 2008
- Package Integrity Testing following accelerated aging per ASTM F1980-07(2011) per AAMI/ANSI/ISO 11607-1:2006/A1:2014 and 11607-2:2006/A1:2014, ASTM F929-15, ASTM F88/F88M-15, and ASTM F1886/F1886M-09(2013)
- Endotoxin Evaluation per ANSI/AAMI ST72:2011/(R)2016 and USP <85>
- Mouse Embryo Assay (MEA)
- Thermal Profile Evaluation
    - The purpose of this test was to evaluate the cooling and warming rates of the subject device, and to demonstrate that these rates are equivalent, or faster, than the predicate device. Temperature recording and graphing equipment was used to record and document the temperature profile of the devices when used as prescribed in the Instructions for Use (IFU) throughout the cooling and warming portions of the vitrification process. The acceptance criteria were that the subject device warming and cooling rates must be substantially equal to (or greater than in absolute value) to the predicate device. The subject device met the acceptance criteria.
- Mouse Embryo Survival Evaluation
    - The purpose of this test was to evaluate post-warming survival rates of various mouse embryos after vitrification using the subject device and predicate device. The vitrification process was performed on mouse embryos according to the device IFU. After warming, all embryos were evaluated for survival rate. The acceptance criteria were that the subject device survival rate must be ≥80% for all embryos stages. The subject device met the acceptance criteria.
- Mouse Embryo Development Evaluation
    - The purpose of this evaluation was to evaluate the post-warming development competence of various mouse embryos after vitrification using the subject device and the predicate device. Embryos were cultured to the blastocyst stage. The acceptance criteria were that the subject device blastocyst development rate must be ≥80% for all embryo stages. The subject device met the acceptance criteria.
- Container and Closure Integrity – Bacterial/Immersion
    - The purpose of this test was to evaluate the microbial barrier of the closure system of the subject device and predicate device. Test samples were transferred to bacterial culture and transferred to an incubator for immersion. After immersion, test samples were removed and examined for growth/turbidity. The acceptance criteria were that the subject device must be

negative for growth of the challenge organism. The subject device met the acceptance criteria.

- Container and Closure Integrity – Bacterial Contaminated LN2
  - The purpose of this test was to evaluate seal integrity through device exposure to bacterial contaminated Liquid Nitrogen (LN_2). The samples were capped as prescribed in the IFU and transferred to contaminated LN_2. Samples were incubated and observed for growth. The acceptance criteria were that the test samples do not show presence or growth of the challenge organism. The subject device met the acceptance criteria. No leakage of LN_2 was observed in the device.
- Durability Testing
  - The purpose of this test was to compare the seal integrity of the subject device to the predicate device by characterizing the seal integrity through exposure to Liquid Nitrogen (LN_2). The samples were assembled as prescribed in the IFU and submerged in LN_2. The test samples were then exposed to 37°C temperatures. The acceptance criteria were that the subject device must not exhibit any cap expulsion during this process. The subject device met the acceptance criteria. No leakage of LN_2 was observed in the device.
- Product Evaluation
  - The purpose of this test was to evaluate the subject device with regards to loading, vitrification, and unloading, following the steps prescribed by the IFU. The acceptance criteria were that that device passes the predetermined design requirements. The subject device met the acceptance criteria.
- Shelf Life Testing – accelerated aging per ASTM F1980-07(2011)
  - Mouse Embryo Assay (MEA)
  - Container and Closure Integrity – Bacterial/Immersion
  - Container and Closure Integrity – Bacterial Contaminated LN2
  - Durability Testing
  - Product Evaluation

Conclusion

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