May 4, 2018

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

Re: K180740
Trade/Device Name: VitriGuard™
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: II
Product Code: MQK
Dated: April 24, 2018
Received: April 25, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K180740

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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# 510(k) Summary
# K180740

**Submitter Information**

Company Name: ORIGIO a/s
Company Address: Knardrupvej 2
2760 Måløv
Denmark
Telephone: +45 46 79 02 00
Fax: +45 46 79 03 02

**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: May 3, 2018

**Device Information**

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

**Predicate Device Information**

ORIGIO a/s VitriGuard (K162833).

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. It is single-use, disposable, and provided sterile. The device consists 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, and capped prior to plunging the device in liquid nitrogen and for subsequent storage. The tip has a trough

area for loading, maintaining, and securing the embryos. The stick and cap include a taper design that creates a seal when assembled. Markings at the end of the stick and the tip of the device provide visual aid for proper device orientation.

Product specifications are listed in Table 1 below:

**Table 1: Product Specifications**

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

**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**

Table 2 provides a comparison of the subject and predicate device.

**Table 2: Comparison of the Subject VitriGuard to the Predicate VitriGuard**

| Property | Subject VitriGuard | Predicate VitriGuard |
|---|---|---|
| **510(k) Number** | K180740 | K162833 |
| **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 | Same |
| **Fundamental Scientific Technology** | The device is composed of a two-piece assembly that includes a stick and cap. As part of the vitrification procedure, the embryos to be stored are loaded on the tip of the stick and capped for subsequent storage. | Same |
| **Material** | Polystyrene (clear, blue, green, yellow, orange, pink, lime green, and purple)<br><br>Black marker bands | Polystyrene (clear, blue, green, and yellow)<br><br>Black marker bands |
| **Sterilization Method** | Radiation | Same |
| **Number of Uses** | Single Use, Disposable | Same |
| **Packaging** | Box of 20 (individually pouched) or box of 50 (5 per pouch) | Box of 20 (individually pouched) |
| **Shelf Life** | One Year | Three Years |

The subject and predicate devices have the same intended use and are technologically comparable. Differences between the predicate and subject device includes the subject device having additional color

options of the stick component, a package configuration including five VitriGuard devices in a pouch, and a reduced shelf-life as compared to the predicate device. These differences do not raise different questions of safety and effectiveness as compared to the predicate device.

**Non-Clinical Performance Testing**

As part of demonstrating substantial equivalence to the predicate, the following tests were performed:

- MEA was performed on VitriGuard devices that were unaged and after one year of accelerated aging per ASTM F1980-07(2011). One-cell mouse embryos were exposed to subject devices and cultured at 37°C in an atmosphere containing 5% CO2. The percent of embryos developed to the expanded blastocyst stage within 96 hours were assessed in comparison with the control group. The subject device met the predetermined acceptance criteria (see Table 1).

- Risk assessment to apply sterilization validation and bioburden testing on the predicate device to the subject device

- Shipping and Distribution Testing per ISTA 3A 2008

- Package Integrity Testing Following Accelerated Aging
  - ASTM F1980-07(2011)
  - ASTM F1929-15
  - ASTM F88/F88M-15
  - ASTM F1886/F1866M-09(2013)

**Conclusion**

The results of the performance testing provided demonstrated that the subject devices are as safe and effective as the predicate devices and supports substantial equivalence.