June 25, 2020

ORIGIO a/s
% Christine Kupchick
Regulatory Affairs Associate
CooperSurgical, Inc.
95 Corporate Drive
Trumbull, CT 06611

Re: K200815
Trade/Device Name: VitriGuard
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: II
Product Code: MQK
Dated: March 27, 2020
Received: March 30, 2020

Dear Christine Kupchick:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Monica D. Garcia, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K200815

Device Name
VitriGuard

Indications for Use *(Describe)*
VitriGuard is intended for use as a cryopreservation storage device in vitrification procedures and indicated to contain and maintain human oocytes (MII), 4-8 cell embryos 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.

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510(k) SUMMARY
K200815

SUBMITTER INFORMATION

Company Name: ORIGIO a/s
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SUBMISSION CORRESPONDENT

Company Name: CooperSurgical Inc.
Company Address: 95 Corporate Drive
Trumbull, CT 06611

SUBMISSION CONTACT

Name: Christine Kupchick
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Date Prepared: June 24, 2020

DEVICE IDENTIFICATION

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: Class II
Review Panel: Obstetrics/Gynecology

PREDICATE DEVICE INFORMATION

Vitrolife Rapid-I (K181461).

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

DEVICE DESCRIPTION

VitriGuard is a sterile, single-use device that is intended for use as a cryopreservation storage device in vitrification procedures. The device consists of a two-piece polystyrene assembly that includes a hexagonal-shaped stick and cap. As part of the vitrification procedure, the oocytes or embryos are loaded on the tip of the stick and the stick is capped prior to plunging the device in liquid nitrogen and for subsequent storage. The tip has a trough area for loading, maintaining and securing oocytes or embryos. The stick and cap include a taper design that create a seal when assembled. Black markings at

the end of the stick and the tip of the device provide visual aid for proper device orientation. All VitriGuard devices have a blue cap and the sticks are available in eight (8) translucent colors: clear, blue, green, yellow, lime green, purple, orange and pink.

INDICATIONS FOR USE

VitriGuard is intended for use as a cryopreservation storage device in vitrification procedures and indicated to contain and maintain human oocytes (MII), 4-8 cell embryos and blastocyst stage embryos.

SUBSTANTIAL EQUIVALENCE DISCUSSION

The table below provides a comparison of the intended use and technological characteristics of the subject and predicate device.

Substantial Equivalence Comparison

Attribute	Subject VitriGuard	Predicate Rapid-I (K181461)
Indications for Use	VitriGuard is intended for use as a cryopreservation storage device in vitrification procedures and indicated to contain and maintain human oocytes (MII), 4-8 cell embryos and blastocyst stage embryos.	Cryopreservation device intended to be used to contain, vitrify and maintain human embryos and/or oocytes (MII).
Fundamental Technology	The device is composed of a two-piece assembly that includes a stick and cap. As part of the vitrification procedure, specimens to be stored are loaded on the tip of the stick and the stick is inserted into the pre-cooled cap to seal and to vitrify samples for subsequent storage in LN.	The stick has a tip where the samples are loaded. The stick is sealed within a pre-cooled straw that contains a stainless-steel weight to maintain device orientation in LN. The stick is inserted into the pre-cooled straw (after steel rod removal) to vitrify samples. The end of the straw is sealed, and the device is stored in LN.
Warming Rate	-2,271°C/min	-1,400°C/min
Cooling Rate	36,377°C/min	10,000°C/min
Endotoxin	≤2.0 EU/device	≤1.0 EU/device
MEA (1-Cell)	≥80% embryos developed to expanded blastocyst at 96h	≥80% embryos developed to expanded blastocyst at 96h
Materials	Polystyrene (clear, blue, green, yellow, orange, pink, lime green, and purple) with black marker bands	Polymethyl methacrylate (PMMA) Mediprene Stainless steel
Sterilization Method	Radiation, SAL 10^{-6}	Ethylene Oxide, SAL 10^{-6}
Number of Uses	Single-use, disposable	Single-use, disposable

The subject and predicate device have similar indications for use statements and have the same intended use – the vitrification and storage of human oocytes (MII) and embryos.

The subject and predicate device have comparable technological characteristics: samples are loaded at the tip, the stick is inserted into a pre-cooled device component, samples are vitrified, and the sealed device with the vitrified samples is placed in Liquid Nitrogen for subsequent storage. The subject device is identical to the predicate in MEA specifications, SAL, and number of uses. The subject device differs

from the predicate in cooling/warming rates, endotoxin specifications, materials, and sterilization method, however, these differences do not raise different questions of safety and effectiveness.

NON-CLINICAL PERFORMANCE TESTING

The following performance testing was leveraged from the original VitriGuard (K162833) to support the performance of the subject device.

- **Sterilization**
  - Validation per ISO 11137-1:2006/(R)2010 and ISO 11137-2:2013
  - Bioburden per ISO 11737-1:2006/(R)2011 and ISO 11737-2:2009
- **Shelf Life Testing**
  - Accelerated aging per ASTM F1980-07(2011)
  - Package Integrity Testing following accelerated aging
    - Dye Penetration Testing per ASTM F2096-11
    - Seal Tensile Strength Testing per ASTM F88/F88M-15
    - Seal Peel Testing per ASTM F1886/F1866M-09(2013)
- **Ship Testing per ISTA 3A:2008**
- **Endotoxin per USP <85> and ANSI/AAMI ST72:2002/(R)2010**
- **Mouse Embryo Assay (MEA)**
- **Thermal Profile Evaluation**
  - Assessment of warming and cooling rates
  - Comparison of warming and cooling rates to other devices cleared for oocyte and embryo vitrification
- **Mouse Embryo Survival Evaluation**
- **Mouse Embryo Development Evaluation**
- **Container and Closure Integrity**
  - Bacterial/Immersion
  - Bacterial Contaminated LN_2
- **Durability Testing**
- **Product Evaluation**

PUBLISHED LITERATURE REVIEW

To support the use of the VitriGuard for the vitrification of MII oocytes, published literature was summarized to assess the VitriGuard, as well as other legally marketed, closed-system devices similar to the subject device in technological characteristics and indicated to contain and maintain human oocytes during vitrification procedures. A summary of the results is shown below:

- **Literature 1:** This study evaluated the efficacy of a closed-system vitrification device for oocyte vitrification as compared to an open-system device. The results of the study show a 93.9% survival rate, 80.6% fertilization rate, 96% cleavage rate and 72% blastocyst development rate after using a closed- system device similar to the subject device. Results are based on 33 vitrified/ warmed donated oocytes using the closed-system device.[1]

- **Literature 2:** This study evaluated the efficacy of a closed-system vitrification device for oocyte vitrification as compared to an open-system device. The results of the study show a 94.5% survival rate, 57.1% fertilization rate, 24.2% implantation rate, 40% clinical pregnancy rate and 37.5% live birth rate after using a closed-system vitrification device similar to the subject device.

Results are based on 498 vitrified/warmed donated oocytes using the closed-system device, which were fertilized/ cultured and transferred to 40 recipients.[2]

- **Literature 3:** This study analyzed oocyte survival rates after warming, and birth outcome of a vitrification protocol in conjunction with a closed-system device. The results of the study show a 94.2% survival rate, 80.4% fertilization rate, 95.1% cleavage rate, 36.1% blastocyst development rate, and 57.1% live birth rate after using a closed-system vitrification device similar to the subject device. Results are based on 190 vitrified/warmed autologous oocytes using the closed-system device, which were fertilized/ cultured and transferred back to the mother (N=14).[3]

- **Literature 4:** This study reported on clinical experience after introducing a closed-system device for oocyte vitrification in daily routine. The overall results of the study show a 90.5% survival rate, 64.2% fertilization rate, 90.4% cleavage rate, 32.7% implantation rate, and 40.9% clinical pregnancy rate after using a closed-system vitrification device similar to the subject device; with results varying depending on maternal age (<38 yrs. versus ≥38 yrs.), including clinical pregnancy rates of 41.9% and 38.5% respectively. [4]

- **Literature 5:** This study evaluated the efficacy of a closed-system vitrification device for oocyte vitrification as compared to an open-system device based on donated oocytes. The results of the study show a 92.1% survival rate after using a closed-system vitrification device similar to the subject device. Results are based on 89 vitrified/ warmed donated oocytes using the closed-system device.[5]

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[1] Inoue (2014) Efficiency of a closed vitrification system with oocytes and blastocysts.
[2] Pujol (2019) Comparison of two different oocyte vitrification methods: a prospective, paired study on the same genetic background and stimulation protocol.
[3] Perez et al (2018) Oocyte vitrification using a new vitrification medium and a new closed vitrification device. A sibling oocyte study.
[4] Gook et al (2016) Closed vitrification of human oocytes and blastocysts: outcomes from a series of clinical cases.
[5] Pinasco et al (2012) Oocyte vitrification freeze/thaw survival rates using an open versus closed system.

- **Literature 6:** This study evaluated if long-term cryopreservation (median 3.5 years storage) of human oocytes affects oocyte developmental competence, blastocyst euploidy, or live-birth rates. The results of the study show an overall 80.4% survival rate, 72.8% fertilization rate, 54.5% blastocyst development rate, 65% implantation rate, 62.5% clinical pregnancy rate and 62.5% live birth rate (including some ongoing pregnancies). Data include the use of a closed-system vitrification device similar to the subject device. Results are based on total 33 patients ending up with 16 embryo transfer cycles.[6]

The published data summarized for closed-system vitrification devices similar to the subject device demonstrates the safe and effective use of the closed-system vitrification devices for oocyte cryopreservation and storage. Furthermore, a cooling/warming rate comparison demonstrates that the subject device has similar cooling/warming rates to other devices that have been cleared for oocyte vitrification and storage. Therefore, the clinical information provided above can be leveraged to demonstrate substantial equivalence to the predicate device and supports the safe and effective use of the subject device for oocyte cryopreservation and storage.

CONCLUSION

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

[6] Goldman et al (2015) Long-term cryopreservation of human oocytes does not increase embryonic aneuploidy.