March 8, 2024

Cook Incorporated
Christopher Sontag
Regulatory Scientist 1
750 Daniels Way
Bloomington, Indiana 47404

Re: K233177
Trade/Device Name: Nest VT Vitrification Device
Regulation Number: 21 CFR 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: II
Product Code: MQK
Received: February 9, 2024

Dear Christopher Sontag:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Michael T. Bailey -S

For
Monica D. Garcia, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233177

Device Name
Nest VT Vitrification Device

Indications for Use *(Describe)*
The Nest VT Vitrification Device is a cryopreservation storage device intended for use in vitrification procedures 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
K233177

1. Submitter Information

Applicant: Cook Inc.
Address: 750 Daniels Way
P.O. Box 489
Bloomington, IN 47402

2. Submission Correspondent

Contact: Christopher Sontag
Email: Chris.Sontag@CookMedical.com
RegSubmissions@cookmedical.com

3. Date prepared: March 7, 2024

4. Device Information

Device Name:	Nest VT Vitrification Device
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

5. Predicate Device Information

Device Name:	VitriGuard
510(k) Number:	K200815
Sponsor:	CooperSurgical Inc.

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

6. Device Description

The subject devices, Cook Nest VT Vitrification Devices, are sterile, single-use assisted reproduction storage devices for use in vitrification procedures to contain and maintain oocytes (MII), 4-8 cell embryos, and blastocyst stage embryos.

The Cook Nest VT Vitrification Devices are composed of a stick (124.5 mm) and cap (38.5 mm) design with a combined length of 136.5 mm, a 35 mm space for notations, and a 6 mm long loading well. Visible marks are on the distal tip end, on the body of the stick and at the opening of the cap, which are created through laser etching to indicate the location of the tip, the upright orientation of the device and the opening of the cap, respectively. The stick and cap include a taper design that create a seal when assembled. All the subject devices included in this submission are identical except

for their color. There are 5 different colors: blue, purple, red, yellow, and green. The subject devices are sterilized using gamma radiation to a sterilization assurance level of 10^{-6}, are one-time use, and have a 2 year shelf-life.

During 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.

7. Indications for Use Statement

The Nest VT Vitrification Device is a cryopreservation storage device intended for use in vitrification procedures to contain and maintain human oocytes (MII), 4-8 cell embryos and blastocyst stage embryos.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below includes a comparison of the intended use and technological characteristics of the subject and predicate devices.

	K233177	**K200815**	**Comparison**
Regulation Number	21 CFR 884.6160	21 CFR 884.6160	Same
Product Code	MQK	MQK	Same
Classification	Class II	Class II	Same
Indications for Use	The Nest VT Vitrification Device is a cryopreservation storage device intended for use in vitrification procedures to contain and maintain human oocytes (MII), 4-8 cell embryos and blastocyst stage embryos.	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.	Same intended use
Design	Stick with cap, design feature to allow handling with forceps	Stick with cap, design feature to allow handling with forceps	Same
Marks/etching	Marks on distal tip end, on body of the stick and at the opening of the cap	Black markings at the end of the stick and the tip of the device	**Different**
Stick material	MBS Copolymer	Polystyrene	**Different**
Cap material	MBS Copolymer	Polystyrene	**Different**
Media Loading volume	1.0 microliter	<0.5 microliter	**Different**
Vitrification system	Closed	Closed	Same

Cooling rate	-1744 ºC/min	-2271ºC/min	**Different**
Warming rate	48818 ºC/min	36377 ºC/min	**Different**
Single use	Yes	Yes	Same
Sterilization method	Gamma	Gamma	Same
Sterilization assurance level	SAL 10^{-6}	SAL 10^{-6}	Same
Endotoxin tested	≤2 EU/device	≤2 EU/device	Same
MEA testing	1-Cell MEA was ≥80% embryos expanded to blastocyst at 96 hours	Yes, ≥80% expand blast within 96 hours	Same

As shown in the table above, there are differences in the subject and predicate device indications for use statements; however, they have the same intended use (i.e., vitrification and storage of human oocytes (MII), 4-8 cell embryos, and blastocyst stage embryos).

The subject and predicate devices also have differences in technological characteristics, including cooling/warming rate, stick composition, loading volume, and available markings. These technological differences do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Sterilization Testing:
Sterilization information was provided in accordance with the 2016 FDA guidance "Submission and Review of Sterility Information in Premarket Notification (510(k) Submissions for Devices Labeled as Sterile." The subject devices are subjected to a Gamma sterilization process to achieve a Sterility Assurance Level (SAL) of 10^{-6}. The sterilization cycle was validated per VDmax25 (for 25 kGy dose) in accordance with ISO 11137-1:2006 and 11137-2:2013.

Simulated Transportation:
Simulated transportation was performed after accelerated aging per ASTM D4169-22.

Endotoxin
Evaluation performed on unaged devices using the Gel-Clot Limulus Amoebocyte Lysate (LAL) method per ANSI/AAMI ST72:2011. The acceptance criterion was ≤ 2 EU/device.

Cooling/warming rate
A comparative analysis was provided on unaged subject devices against the predicate, K200815, to verify cooling/warming rates for closed vitrification storage after immersion and removal from liquid nitrogen. The subject device performed within the specifications noted in the table above.

Stability and Shelf Life:
The following tests were completed to demonstrate that the subject devices maintained their performance in newly manufactured devices and after 2-years of accelerated aging per ASTM F1980-21 and simulated transportation:

- Mouse embryo assay (MEA) – Testing conducted in accordance with the 2021 FDA guidance "Mouse Embryo Assay for Assisted Reproduction Technology Devices." The acceptance criterion for the 1-Cell MEA was ≥80% embryos expanded to blastocyst at 96 hours.

- Package Integrity Testing:
  - F1886/F1886M-16
  - ASTM F88/F88M-15
  - ASTM F1929-15
- Mechanical Performance Testing:
  - Dimensional testing
  - Examination following cryostorage
  - Seal integrity and leakage assessment following cryostorage
  - Capping force and torque testing
  - Uncapping force and torque testing

10. Conclusion

The results of the performance testing described above demonstrate that the subject devices are as safe and effective as the predicate device and support a determination of substantial equivalence.