April 11, 2018

Cook Incorporated
Naomi Funkhouser, MBA
Regulatory Affairs Specialist/Scientist
750 Daniels Way P.O. Box 489
Bloomington, IN 47402

Re: K173686
Trade/Device Name: Guardia Access Embryo Transfer Catheter Sets and Sydney IVF® Transfer Catheter
Regulation Number: 21 CFR§ 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: II
Product Code: MQF
Dated: March 9, 2018
Received: March 13, 2018

Dear Naomi Funkhouser:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173686

Device Name

Guardia Access Embryo Transfer Catheter Sets and Sydney IVF® Transfer Catheter

Indications for Use *(Describe)*
Guardia Access Embryo Transfer Catheter Sets and Sydney IVF® Transfer Catheter:
Used to place in vitro fertilized (IVF) embryos into the uterine cavity.

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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510(k) Summary – K173686

Submitted By:

Applicant: Cook Incorporated
Contacts: Naomi Funkhouser
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Contact Phone: (812) 339-2235 x104371
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Date Prepared: April 9, 2018

Device Information:

Trade Names: Guardia Access Embryo Transfer Catheter Sets and Sydney IVF® Transfer Catheter
Common Name: Embryo Transfer Catheter
Classification Name: Assisted Reproduction Catheters (21 CFR 884.6110)
Classification Regulation: MQF (Catheter, Assisted Reproduction)
Regulatory Class II

Predicate Device:

Embryo Transfer Catheter/Sets (K983594) manufactured by Cook Ob/Gyn. This predicate device has not been subject to any design related recalls.

Device Description:

The Guardia Access Embryo Transfer Catheter Sets and Sydney IVF® Transfer Catheter cover six subject devices from two of COOK's device families, Guardia™ Access and Guardia™, as outlined in the table below:

Product family	Device	Product Number	Component
Guardia™ Access	Guardia™ Access Embryo Transfer Catheter	K-JETS-6019	Embryo transfer catheter and guide catheter
	Guardia™ Access Embryo Transfer Catheter with Internal Supporting Cannula	K-JETS-7019-INT	Embryo transfer catheter and guide catheter
	Guardia™ Access Embryo Transfer Catheter	K-JETS-7019	Embryo transfer catheter and guide catheter
	Guardia™ AccessET Embryo Transfer Catheter	K-JETS-6019-ET	Embryo transfer catheter and guide catheter
	Guardia™ AccessET Embryo Transfer Catheter	K-JETS-7019-ET	Embryo transfer catheter and guide catheter
Guardia™	Sydney IVF® Embryo Transfer Catheter	K-JET-2823	Embryo transfer catheter

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All embryo transfer catheters have an outer diameter of 2.8 Fr and range in length from 23 to 25 cm. The transfer catheters have internal or external supporting cannula, depth indicators, and may have an echogenic band. The Guardia™ Access guide catheters are precurved and feature a bulb-shaped tip. They measure 6.6 Fr in outer diameter and are 16.7 to 17.3 cm in length.

All subject devices are single-use devices and sterilized by ethylene oxide exposure. They undergo lot release Mouse Embryo Assay (MEA) testing for embryo toxicity and USP endotoxin (LAL) testing for pyrogenicity. The subject devices are packaged in peel-open sterile barrier pouches with a three-year shelf life.

Indications for Use:

Guardia Access Embryo Transfer Catheter Sets and Sydney IVF® Transfer Catheter:

Used to place in vitro fertilized (IVF) embryos into the uterine cavity.

Comparison of Intended Use and Technological Characteristics with the Predicate Device:

Parameter	K173686 (subject device)	K983594 (predicate device)
Indication for Use	Used to place in vitro fertilized (IVF) embryos in the uterine cavity.	The embryo transfer catheters/sets are used to place embryos in the uterine cavity.
Design – transfer catheter	Same as predicate	• Graduation marks • Open end • Locking hub • With or without echotip
Design – guide catheter	Same as predicate	• No graduation marks • Positioner • Bulb tip • Precurved • No echotip
Dimension – transfer catheter	OD 2.8 Fr / Length 23-25 cm	OD 2-8 Fr / Length 12-30 cm
Dimensions – guide catheter	OD 6.6 Fr / Length 16.7 or 17.3 cm	OD 5-8.5 Fr / Length 12-30 cm
Materials – transfer catheter	Polyethylene, polyurethane, stainless steel	Polyethylene, teflon, stainless steel
Materials – guide catheter	Polyurethane, silicone, polymethylpentene	Polyethylene, echosight polyethylene, teflon, stainless steel

The subject and predicate devices have the same intended use. They also have the comparable designs. There are differences in dimensions and materials between the subject and predicate devices, but these differences do not raise different questions of safety and effectiveness. The difference in dimensions can be addressed by bench performance testing. The differences in materials can be evaluated by biocompatibility testing and Mouse Embryo Assay Testing.

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Summary of Non-Clinical Performance Testing:

The following studies have been performed to support substantial equivalence to the predicate device:

- Sterilization Validation testing per ISO 11135-1:2007
- Biocompatibility studies, as follows:
  - Cytotoxicity testing per 10993-5:2009
  - Guinea Pig Maximization Sensitization testing per ISO 10993-10:2002 or ISO 10993-10:2010
  - Intracutaneous Irritation testing per ISO 10993-10:2002 or ISO 10993-10:2010
- Endotoxin testing per USP <85> and AAMI/ANSI ST72:2011/(R)2016 (<20 EU/device)
- Transportation Simulation study per ASTM D4169-05
- Package Integrity testing after real-time aging:
  - Bubble Leak test per ASTM F2096-04
  - Seal Strength testing per ASTM F88-09
  - Visual Inspection: No package displayed damage (tears, folds, puncture holes, etc.)
- Mouse Embryo Assay (MEA) before and after aging:

  One-cell mouse embryos were exposed to subject devices and cultured at 37°C in an atmosphere containing 5% CO_2. The percent of embryos developed to the expanded blastocyst stage within 96 hours were assessed in comparison with the control group. The testing demonstrated that the devices met acceptance criterion of "1-cell MEA ≥80% embryos developed to blastocyst in 96 hours."
- Bench Performance studies before and after aging demondtrated that all predetermined acceptance criteria were met in the following tests:
  - Dimensional verification of catheter – Catheters are measured and verified against device input requirements.
  - Transfer Catheter Aspiration Test – Testing ensures there is no air leaking into the syringe through the transfer catheter.
  - Transfer Catheter Leak Test – Testing ensures that fluid path catheter assembly does not leak under a predetermined injection pressure.
  - Tensile Testing (Catheter Hub- shaft) – Testing demonstates that the tensile strength value is greater than the predetermined acceptance criterion.
  - Echotip Band Test – Testing ensures that the outer diameter of the band does not impede smooth passage through the guide catheter.
  - Echotip Band Echogenicity Test – Visual comparison testing by ultrasound imaging of catheters with and without an EchoTip band verified that the band provides increased brightness.

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Conclusion:

The subject and predicate devices have the same intended use. Although there are differences in technological characteristics between the subject and predicate devices, these differences do not raise different questions of safety or effectiveness. The performance data demonstrate that the subject devices are substantially equivalent to the predicate device.