January 10, 2018

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

Re: K172051
Trade/Device Name: Guardia™ Access Nano and Soft-Trans Embryo Transfer Catheter Sets, Soft-Trans Embryo Transfer Catheter, Soft-Trans Guide Catheter
Regulation Number: 21 CFR§ 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: II
Product Code: MQF
Dated: December 8, 2017
Received: December 11, 2017

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)*
K172051

Device Name

Guardia™ Access Nano and Soft-Trans Embryo Transfer Catheter Sets

Indications for Use *(Describe)*

Guardia™ Access Nano and Soft-Trans Embryo Transfer Catheter Sets:

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.

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

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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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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)*
K172051

Device Name

Soft-Trans Embryo Transfer Catheter

Indications for Use *(Describe)*

Soft-Trans Embryo Transfer Catheter:

Used to place in vitro fertilized (IVF) embryos into the uterine cavity. This device is to be used in combination with a cleared, dimensionally compatible Embryo Transfer Guide Catheter for gaining access to 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)

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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)*
K172051

Device Name

Soft-Trans Guide Catheter

Indications for Use *(Describe)*

Soft-Trans Guide Catheter:

Used to supplement and assist uterine access of a cleared, dimensionally compatible Embryo Transfer Catheter for placement of 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)

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510(k) Summary – K172051

Submitted By:

Applicant:	Cook Incorporated
Contacts:	Naomi Funkhouser Rohini Patel
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone:	(812) 339-2235 x104371
Contact Fax:	(812) 332-0281

Date Prepared: January 8, 2018

Device Information:

Trade Names:	Guardia™ Access Nano and Soft-Trans Embryo Transfer Catheter Sets, Soft-Trans Embryo Transfer Catheter, Soft-Trans Guide Catheter
Common Name:	Embryo Transfer Catheter
Classification Name:	Assisted Reproduction Catheters (21 CFR 884.6110)
Product Code:	MQF (Catheter, Assisted Reproduction)
Regulatory Class/Classification Panel:	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:

This 510(k) covers the following subject devices:

Device	RPN	Component
Guardia™ Access Nano Embryo Transfer Catheter	K-JETS-551910-S	Embryo transfer catheter and guide catheter
Soft-Trans Embryo Transfer Catheter	K-SOFT-5000	Embryo transfer catheter and guide catheter
	K-SOFT-5000-ST	Embryo transfer catheter and guide catheter
	K-SOFT-5010	Guide catheter
	K-SOFT-5100	Embryo transfer catheter
	K-SOFT-5000-TC	Embryo transfer catheter, guide catheter, and trial catheter

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The transfer catheters are manufactured from polyurethane. The Guardia™ Access Nano Embryo Transfer Catheter has a diameter of 2.8 Fr and is 24 cm in length. The Soft-Trans Embryo Transfer Catheters have a diameter of 4.7 Fr and range in length from 19 to 23 cm. Both transfer catheters also include a stainless steel cannula to provide additional support and depth indicators. The Soft-Trans Embryo Transfer Catheter Set (K-SOFT-5000-TC) also includes a closed-ended polycarbonate/polyurethane/stainless steel trial catheter that has a diameter of 4.0 Fr and is 18 cm in length.

The guide catheter for the Guardia™ Access Nano Embryo Transfer Catheter is manufactured from polymethylpentene, and has a diameter of 5.5 Fr and is 17.3 cm in length. This guide catheter also features a bulb tip, silicone position marker, and is provided pre-curved. The guide catheter for the Soft-Trans Embryo Transfer Catheter Sets are manufactured from polyethylene, have a diameter of 8.1 Fr, and are 11.4 or 15.4 cm in length. This guide catheter is provided in a straight configuration.

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

Indications for Use:

Guardia™ Access Nano and Soft-Trans Embryo Transfer Catheter Sets:

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

Soft-Trans Embryo Transfer Catheter:

Used to place in vitro fertilized (IVF) embryos into the uterine cavity. This device is to be used in combination with a cleared, dimensionally compatible Embryo Transfer Guide Catheter for gaining access to the uterine cavity.

Soft-Trans Guide Catheter:

Used to supplement and assist uterine access of a cleared, dimensionally compatible Embryo Transfer Catheter for placement of in vitro fertilized (IVF) embryos into the uterine cavity.

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

Parameter	K172051 (subject device)	K983594 (predicate device)
Intended Use	Same as predicate	The embryo transfer catheters/sets are used to place embryos into the uterine cavity.
Design of transfer catheter	Same as predicate	• Graduation marks • Open end with side port • Locking hubs
Design of guide catheter	Same as predicate	• Graduation marks • Open end with side port • Locking hubs • Precurved or straight • With or without positioner
Design of trial catheter	• Positioning marks • Closed end	N/A
Dimension of transfer catheter	OD 2.8-4.7 Fr Length 19.1-24 cm	OD 2-8 Fr Length 12-30 cm
Dimensions of guide catheter	OD 5.5-8.1 Fr Length 11.4-17.3 cm	OD 5-8.5 Fr Length 12-30 cm
Dimensions of trial catheter	OD 4.0 Fr Length 18 cm	N/A
Materials – Transfer catheter	Polyurethane, Stainless Steel	Polyethylene, Teflon, Stainless Steel
Materials – Guide catheter	Polyethylene, Polymethylpentene	Polyethylene, Echosight Polyethylene, Teflon, Stainless Steel
Material – Trial catheter	Polycarbonate, Stainless Steel, Polyurethane	N/A

The subject and predicate devices have the same intended use. They also have the same design. There are differences in dimensions and materials between the subject and predicate devices, but these differences do not raise any 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 MEA. In addition, one version of the subject Soft-Trans Embryo Transfer Catheter Set (K-SOFT-5000-TC) includes a trial catheter that can be used to assess the placement of the device prior to conducting the actual embryo transfer procedure. The addition of the trial catheter does not raise different questions of safety and effectiveness as compared to the predicate device (ability to deliver the device to the uterine cavity, perforation risks, etc.).

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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 10993-10:2010
  - Intracutaneous Irritation testing per ISO 10993-10:2010
- Endotoxin testing per USP <85> and AAMI/ANSI ST72:2011/(R)2016 (<20 EU/device)
- Transportation Simulation study per ASTM D4169-16
- 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 real-time aging demondtrated that all predetermined acceptance criteria were met in the following tests:
  - Dimensional Verification of Guide Catheter - The guide 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 demonstrated that the tensile strength value was greater than the predetermined acceptance criterion**.**

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.