October 24, 2018

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

Re: K180302
Trade/Device Name: Guardia™ Access Malleable Obturator, Guardia™ Obturator, Soft-Pass™ Obturator, Soft-Trans Malleable Obturator, Guardia™ ETS Embryo-Tested Syringe, Flushing Catheter
Regulation Number: 21 CFR 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: Class II
Product Code: MQF
Dated: September 26, 2018
Received: September 27, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Sharon M. Andrews -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)*
K180302

Device Name
Guardia™ Access Malleable Obturator, Guardia™ Obturator, Soft-Pass™ Obturator, Soft -Trans Malleable Obturator, Guardia™ ETS Embryo-Tested Syringe, Flushing Catheter

Indications for Use *(Describe)*

Guardia™ Access Malleable Obturator, Guardia™ Obturator, Soft-Pass™ Obturator, and Soft -Trans Malleable Obturator:
Used to supplement and assist uterine access of a cleared, dimensionally compatible embryo transfer device for placement of in vitro fertilized (IVF) embryos into the uterine cavity.

Guardia™ ETS Embryo-Tested Syringe:
For use with catheters indicated for intrauterine insemination and embryo transfer.

Flushing Catheter:
The Flushing Catheter is intended for instillation of sterile medium into the cervical canal prior to embryo transfer.

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 – K180302

1. Submitter Information:

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

2. Date Prepared:

October 24, 2018

3. Device Information:

Trade Names:	Guardia™ Access Malleable Obturator, Guardia™ Obturator, Soft-Pass™ Obturator, Soft-Trans Malleable Obturator, Guardia™ ETS Embryo-Tested Syringe, Flushing Catheter
Common Name:	Embryo Transfer Obturators and Accessories
Classification Name:	Assisted Reproduction Catheters (21 CFR 884.6110)
Classification Regulation:	MQF (Catheter, Assisted Reproduction)
Regulatory Class	II

4. Predicate Device:

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

5. Device Description:

This 510(k) covers eight devices from five of COOK's device families. These devices, as outlined in the table below, are sold separately.

Product family	Product name	RPN	Diameter/length or volume
Guardia Access	Guardia™ Access Malleable Obturator	K-JET-7002	4.0 Fr/19.9 cm
Guardia	Guardia™ Obturator (Malleable Adjustable Obturator)	J-UOB-2828	2.8 Fr/28 cm
	Guardia™ Obturator (Malleable Adjustable Obturator)	J-UOB-4028	4.0 Fr/28 cm

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	Guardia™ Obturator (Stiff Adjustable Obturator)	J-UOB-4028-ST	4.0 Fr/28 cm
	Guardia™ ETS Embryo-Tested Syringe	K-ETS-1000	1 ml
Soft-Pass	Soft-Pass™ Obturator	J-SP-4420	4.4 Fr/20.2 cm
Soft-Trans	Soft-Trans Malleable Obturator	K-SOFT-4018	4.0 Fr/18 cm
Flushing Catheter	Flushing Catheter	J-IUIC-352000-CE	3.5 Fr/20 cm

The polyurethane obturators are designed to fit dimensionally compatible embryo transfer guide catheters. Some of these devices are designed to be adjustable in length.

The flushing catheter is a 20 cm tube measuring 14.9 Fr at the proximal end and tapering to 3.5 Fr at the distal end. It features a depth indicator and directional side port with an ink mark aligned with the position of the side port. This device is identical to the Insemi-Cath IUI catheter cleared under K172321.

The Guardia Embryo-Tested Syringe is two-part syringe with a polypropylene barrel and a high-density polyethylene plunger. This device undergoes Mouse Embryo Assay (MEA) and endotoxin testing (LAL) before lot release.

All subject devices are supplied sterile and intended for one-time use. The Guardia Embryo-Tested Syringe has a shelf-life of five years, whereas the remaining subject devices have a shelf-life of three years.

6. Indications for Use:

Guardia™ Access Malleable Obturator, Guardia™ Obturator, Soft-Pass™ Obturator, and Soft-Trans Malleable Obturator:

> Used to supplement and assist uterine access of a cleared, dimensionally compatible embryo transfer device for placement of in vitro fertilized (IVF) embryos into the uterine cavity.

Guardia™ ETS Embryo-Tested Syringe

> For use with catheters indicated for intrauterine insemination and embryo transfer.

Flushing Catheter

> The Flushing Catheter is intended for instillation of sterile medium into the cervical canal prior to embryo transfer.

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

Comparison of obturators with the predicate device

Device	Subject device (K180302)	Predicate device (K983594)
Intended Use	Same as the predicate device	Used to supplement and assist uterine access of cleared, dimensionally compatible embryo transfer devices for placement of in vitro fertilized (IVF) embryos into the uterine cavity.
Design	• Adjustable handles to be sized to fit inside guide catheters • Polyethylene over soft stainless or stylet wire for malleability • Smooth and rounded distal tip	• Sized to fit inside guide catheters • Malleability not specified • Tip characteristic not specified
Dimension	• OD: 2.8-4.4 Fr • Length: 18-28 cm	• OD: Matched to fit within guide catheter • Length: matched with guide catheter at tip
Materials	Same as the predicate device	Polyethylene, stainless steel

Both subject and predicate devices are used to supplement and assist uterine access of cleared, dimensionally compatible embryo transfer devices for placement of IVF embryos into the uterine cavity. Therefore, they have the same intended use.

The subject and predicate devices use the same materials but have different design and dimensions. However, the differences are commonly seen in cleared devices and therefore, do not raise different questions of safety and effectiveness. The differences can be assessed by biocompatibility and bench performance testing.

Comparison of Guardia™ ETS Embryo-Tested Syringe with the predicate device

The predicate device (K983594) includes a syringe intended for aiding in embryo transfer procedures. Therefore, the subject device and predicate devices have the same intended use. In addition, these two devices have comparable technological characteristics. The Guardia™ ETS Embryo-Tested Syringe is identical to a cleared device intended for general injection use. To ensure biological safety, the subject syringe is evaluated for embryotoxicity and endotoxin.

Comparison of Flushing Catheter with the predicate device

Device	Subject device (K180302)	Predicate device (K983594)
Design	• Without graduation marks • Close end with side port • Without hubs • With positioner	• With or without graduation marks • Open end with side port • With or without hubs • Without positioner
Dimension	OD 3.5 Fr / Length 20 cm	OD 2-8 Fr / Length 12-30 cm
Materials	Nylon, silicone	Polyethylene, Teflon, stainless steel

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The subject and predicate devices have similarity in design (e.g., side port, hubless, no graduation marks and comparable dimensions). There are differences in design, materials, and dimensions, but these differences do not raise different questions of safety or effectiveness as compared to the predicate device and are commonly seen in other comparable cleared Assisted Reproduction Technology devices. The differences can be assessed by biocompatibility and bench performance testing.

8. 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 10993-10:2002/2010
  - Intracutaneous Irritation testing per ISO 10993-10:2002/2010
- Endotoxin testing per AAMI/ANSI ST72:2011 (<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. 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 demonstrated that all predetermined acceptance criteria were met in the following tests:
  - Obturator/Flushing Catheter dimensional verification – Devices are measured and verified against device input requirements.
  - Flushing Catheter Leak Test – Testing ensures that fluid path does not leak under a predetermined injection pressure.

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- Obturator/Flushing Catheter Tensile Test – Testing demonstrates that the tensile strength value is greater than the predetermined acceptance criterion.
- Obturator Handle Securement Test – Testing demonstrates the adjustment mechanism does not allow the obturator to move from its set position under worst case handling under the predetermined acceptance criterion.
- Obturator Fracture Test – This testing demonstrated that the test articles do not facture, loosen, or fail when tested in accordance with ISO 11070:1999

In addition, performance data in K172321 and K101547 are leveraged to support substantial equivalence of Flushing Catheter and Guardia™ ETS Embryo-Tested Syringe, respectively.

9. 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.