DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 14, 2017

Cook Incorporated
Naomi N. Funkhouser
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K163318
Trade/Device Name: Soules Intrauterine Insemination Catheter
Regulation Number: 21 CFR 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: Class II
Product Code: MQF, LKF
Dated: June 13, 2017
Received: June 13, 2017

Dear Naomi N. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163318

Device Name

Soules Intrauterine Insemination Catheter

Indications for Use *(Describe)*

The Soules Intrauterine Insemination Catheter is used to access the uterine cavity for saline infusion sonohysterography or for the introduction of washed spermatozoa 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.

COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

510(k) SUMMARY- K163318

Date Prepared: July 11, 2017

Submitted By:

Applicant:	Cook Incorporated
Contact:	Naomi N. Funkhouser
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x10-4371
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	Soules Intrauterine Insemination Catheter
Common Name:	Intrauterine insemination catheter
Classification Name:	Assisted Reproduction Catheters
Regulation Number:	21 CFR §884.6110
Product Code:	MQF (Catheter, Assisted Reproduction) LKF (Cannula, Manipulator/Injector, Uterine)
Product Class:	II

Predicate Device:

K061679 – Wallace SIS/AI Catheter (Irvine Scientific Sales Co., Inc.).
This device has not been subject to a design-related recall.

Device Description:

The Soules Intrauterine Insemination Catheter consists of a 5.3 French polyethylene catheter that is 25 cm in length with a polyethylene female luer adapter hub. The tip of the device features an oval side port located ~2.5 mm from the distal end of the catheter. A 3 mm movable silicone positioner is also present on the shaft of the catheter that can be adjusted to aid in positioning the device to the targeted depth within the uterine cavity during a procedure.

Indication for Use:

The Soules Intrauterine Insemination Catheter is used to access the uterine cavity for saline infusion sonohysterography or for the introduction of washed spermatozoa into the uterine cavity.

Comparison to Predicate:

	K163318- Subject Device	K061679 – Predicate Device
Intended Use		
Indication for Use	The Soules Intrauterine Insemination Catheter is used to access the uterine cavity for saline infusion sonohysterography or for the introduction of washed spermatozoa into the uterine cavity.	The wallace SIS/AI catheter is intended to be used in artifical insemination procedures intended for insertion of the catheter and introduction of washed spermatozoa into the uterine cavity. The wallace sis/ai catheter is also intended to be used in saline infusion sonography (SIS) also known as saline infusion sonohysterography (SIS) and saline ultrasound infusion procedures in the detection abnormalities within uterine cavities.
Technology		
Tubing	Polyethylene	FEP, polyurethane, LDPE, and Nylon
Hub	Polyethylene	Polypropylene and Nylon
Tubing Length, Width	25 cm, 5.3 Fr	18 cm, 16 Gauge (5.0 Fr) – inner catheter.
Device Design	Single lumen catheter with a luer lock	Inner catheter and a detachable outer sheath that attaches to the inner catheter by a luer lock When the outer sheath is attached to the hub of the catheter, the inner catheter protrudes from the distal end of the outer sheath by 5 cm
Side port	Single oval side port 2-3 mm from distal tip	Dual oval Side ports on distal tip
Depth indicator	One adjustable 3 mm silicone band initially placed 7 cm from distal tip of catheter	Five – 1 cm graduations ink marks on outer catheter
Sterilization	EtO	EtO

The subject and predicate device have the same intended use – the delivery of washed spermatozoa to the uterine cavity and SIS. In addition, the subject and predicate devices are similar in some technological features, including design (e.g., tip and hub design), usability, hub adapter, and sterility procedure.

However, there are a number of differences between the subject and predicate device that are described below:

- Device materials – Some of the device materials (e.g., tubing, hub, depth indicator) are not the same. Materials differences are common in ART devices and do not raise different questions of safety and effectiveness, and can be addressed through testing (e.g., biocompatibility, performance).
- Device dimensions – The subject device has differences in device dimensions (e.g., greater length). These differences do not raise different questions of safety or effectiveness.
- Device Design– The subject device has an adjustable silicone depth indicator whereas the predicate device has five graduation ink marks on the catheter. In addition, the subject device has a single side port whereas the predicate device a double side port. The subject device is a single catheter whereas the predicate device has an inner catheter with a detachable outer sheath that attaches to the inner catheter. The differences between the device designs do not raise different questions of safety and effectiveness (e.g., ability to access the uterine cavity, risk of perforation, etc.).

Performance Testing:

The following tests were performed to demonstrate that the proposed Soules Intrauterine Insemination Catheter met the applicable design and performance requirements and support a determination of substantial equivalence under the specified testing parameters. These tests include:

1. Sterilization Validation per ISO 11135-1:2007 and ISO 10993-7: 2008.
2. Package integrity testing following real-time aging:
    - Bubble leak test per ASTM F2096-04
    - Seal strength testing per ASTM F88-09
    - Visual Inspection per ASTM F1886-09

3. Human Sperm Survival Assay – Testing ensures manufacturing materials do not have an adverse effect upon the survival of Human Sperm. Test articles assessed provided acceptable results of ≥ 70% motility at 24 hours.
4. Endotoxin Assay – (AAMI ST72: 2011 and UPS/NF <85>) ≤20 EU/device less
5. Dimensional Analysis - Testing was performed with the requirement that specific product dimensions should be within set tolerances. The results showed that the predetermined acceptance criteria were met.
6. Injection Leak – Testing completed to ensure the device can withstand pressure from injection.
7. Air Aspiration – Testing completed to ensure the device does not leak during aspiration. The predetermined acceptance criterion was met.
8. Tensile Test – Testing ensures the tensile strength of the hub to shaft bond.
9. Biocompatibility - Biocompatibility testing was conducted according to ISO 10993-1- 2009. Testing included cytotoxicity (ISO 10993-5:2009), intracutaneous reactivity (ISO 10993-10:2010), and sensitization (ISO 10993-10:2010). The test articles assessed provided acceptable results as no signs of cytotoxicity, sensitization or irritation reactions were noted in testing.
10. Shelf-life testing was conducted to ensure that the following product specifications were met to support a three-year shelf-life:
    - Tensile testing
    - Injection leak testing
    - Dimensional analysis
    - HSSA testing
    - Air Aspiration

Conclusion:

The results of the testing described above demonstrate that the Soules Intrauterine Insemination Catheter is as safe and effective as the predicate device and supports a determination of substantial equivalence.