December 21, 2017

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

Re: K172321
Trade/Device Name: Shepard, Insemi-Cath®, and Soft-Pass™ Coaxial - Cook Intrauterine Insemination Catheters
Regulation Number: 21 CFR§ 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: II
Product Code: MQF
Dated: November 27, 2017
Received: November 28, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172321

Device Name

Shepard, Insemi-Cath®, and Soft-Pass™ Coaxial - Cook Intrauterine Insemination Catheters

Indications for Use *(Describe)*

Intrauterine Insemination Catheters are used 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.

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510(k) Summary – K172321

Shepard,
Insemi-Cath®,
and Soft-Pass™ Coaxial
Cook Intrauterine Insemination Catheters

Date Prepared: December 20, 2017

Submitted By:

Applicant:	Cook Incorporated
Contact:	Naomi Funkhouser, Rohini Patel
Applicant Address:	750 Daniels Way P.O. Box 489 Bloomington, IN 47402
Contact Phone Number:	(812) 339-2235 x104371
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	Shepard, Insemi-Cath®, and Soft-Pass™ Coaxial – Cook Intrauterine Insemination Catheters
Common Name:	Intrauterine Insemination Catheters
Classification Name:	Assisted Reproduction Catheters
Classification Number:	884.6110
Product Code:	MQF – Catheter, Assisted Reproduction
Device Class:	Class II
Classification Panel:	Obstetrics/Gynecology

Predicate Devices:

- Shepard IUI Catheter, K890301
- Coaxial Catheter Set, K902694
- Insemi-Cath II, K954398

The predicate devices have not been subject to a design-related recall.

Device Description:

Shepard Intrauterine Insemination Set

The Shepard Intrauterine Insemination Set consists of a 5.4 French polyethylene tubing catheter with a connector cap and a stainless steel inner cannula with a female luer lock adapter (FLLA) hub. The assembled device measures 20 cm in length. A silicone positioner is placed 7 cm from the distal tip. The positioner is adjustable to aid in positioning the device to the targeted depth within the uterine cavity during a procedure.

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The distal end is curved, with a closed ended tip rounded to a smooth finish. One sideport is located just proximal to the distal tip.

Soft-Pass™ Coaxial Insemination Catheter

The Soft-Pass™ Coaxial Insemination Catheter is comprised of a guide catheter and an insemination/transfer catheter. The guide catheter is 6.8 French in diameter and measures 12 cm in length. Ink marks are placed on the distal end of the guide catheter to aid in positioning within the cervical canal. The transfer hub has a female luer adaptor to which the preloaded syringe is affixed. The guide catheter hub and transfer hub connect with a friction fit. The transfer catheter is 4.4 French in diameter.

Insemi-Cath®

The Insemi-Cath® is 3.5 French in diameter and has a length of 13 cm. It is manufactured from nylon tubing that tapers gradually from 0.195 inches at the proximal end that accepts a standard slip tip syringe and tapers for the remaining 7 cm of the catheter. The distal end is manufactured in both curved and straight configurations. The curved Insemi-Cath® features a silicone positioner placed approximately 7 cm from the distal tip. The positioner is adjustable to aid in positioning the device to the targeted depth within the uterine cavity during a procedure. The distal tip of the catheter is rounded to a smooth finish and designed with an open end.

Indications for Use:

Intrauterine Insemination Catheters are used for the introduction of washed spermatozoa into the uterine cavity.

Comparison to Predicate Devices:

The subject Shepard IUI set as compared to the predicate device, Shepard IUI Set (K890301), has the same intended use, and is similar in terms of principles of operation, basic technological characteristics, and design. The dimensions of the device are within the range of the predicate, and with a minor design modification to include a winged FLLA. The hub material of the predicate device was not specified, and the subject device hub material is Polycarbonate.

The subject Soft-Pass™ Coaxial Insemination Catheter as compared to the predicate device, Coaxial Catheter Set (K902694), has the same intended use, and is similar in terms of principles of operation, and basic technological characteristics. The Soft-Pass™

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transfer and guide catheter material was changed to Polyethylene and the hub material to HDPE. The hub design was modified to include a friction fit connection, the silicone positioner was removed, and ink marks were placed on the distal end of the guide catheter, rather than the proximal end of transfer catheter. Finally, the guide catheter size and length dimensions were modified to better function with the Soft-Pass™ insemination catheter.

The Insemi-Cath® is identical to the predicate device the Insemi-Cath® II (K902694). The curved version of the subject device has an added silicone positioner.

Special Controls:

The IUI catheters are subject to special controls and must pass HSSA and endotoxin testing. The testing is conducted on a lot-to-lot (batch) basis.

- Human Sperm Survival Assay (HSSA), ≥70% motility after 24 hours.
- Endotoxin - (LAL) test per AAMI/ANSI ST72:2011/(R) 2016 and USP <85>, < 20 EU/device

The predetermined acceptance criteria were met for these special controls on newly manufactured (HSSA, endotoxin) and aged (HSSA only) devices.

Test Data:

The following tests were performed to demonstrate that the minor modifications to the subject IUI catheters have met applicable design and performance requirements to support a determination of substantial equivalence.

- Catheter Aspiration Test - Testing ensures there is no air leaking into the syringe through the catheter. *All predetermined acceptance criteria were met.*
- Catheter Leak Test - Testing ensures that fluid path catheter assembly does not leak under a predetermined injection pressure. *All predetermined acceptance criteria were met.*
- Tensile Testing (Catheter Hub- shaft) - Testing demonstrated that the tensile strength value was greater than the predetermined acceptance criterion**.** *Acceptance criterion was met.*

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- Biocompatibility - Testing shows that the subject device sets conform to the biocompatibility requirements of ISO 10993-1:2009. The following tests were performed:
    - Cytotoxicity per ISO 10993-5:2009
    - Sensitization per ISO 10993-10:2010
    - Irritation per ISO 10993-10:2010
- Shelf life - accelerated aging per ASTM F1980-16 to demonstrate that the subject device maintains the mechanical and HSSA specifications after three years of aging.
- Package integrity - per ASTM F1886-09 (visual inspection), ASTM F2096-11 (bubble leak), and ASTM F88-09 (seal strength)

Conclusion:

The results of the performance testing support a determination of substantial equivalence of the subject device to the predicate devices, and do not raise any new questions of the safety or effectiveness.