March 29, 2019

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

Re: K181770
Trade/Device Name: Intrauterine Access Balloon Catheter, Selective Salpingography Catheter
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: LKF
Dated: February 27, 2019
Received: February 27, 2019

Dear Ian Herrman:

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,

Jason Roberts -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)*
K181770

Device Name
Intrauterine Access Balloon Catheter

Selective Salpingography Catheter

Indications for Use *(Describe)*
The Intrauterine Access Balloon Catheter is used for delivery of contrast medium into the uterine cavity during hysterosalpingography (HSG) for examination of the uterus and fallopian tubes, and evaluation of tubal patency. The catheter lumen accepts catheters up to 6 French in diameter to access the uterine cavity for assessment of tubal patency.

The Selective Salpingography Catheter is intended to be used through a uterine access device and positioned at the tubal ostium for injection of contrast medium for fluoroscopic evaluation of tubal patency.

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
K181770

Intrauterine Access Balloon Catheter
Selective Salpingography Catheter
Date Prepared: March 26, 2019

Submitted By:

Applicant:	Cook Incorporated
Contact:	Ian Herrman, Rohini Patel
Applicant Address:	Cook Incorporated 750 Daniels Way P.O. Box 489 Bloomington, IN 47402 Phone: (812) 335-3575 x104034 Fax: (812) 332-0281

Device Information:

Trade Name:	Intrauterine Access Balloon Catheter Selective Salpingography Catheter
Common Name:	Hysterosalpingography Catheters
Regulation Number:	21 CFR §884.4530
Regulation Name:	Obstetric-gynecologic specialized manual instrument
Product Code:	LKF, Cannula, Manipulator/Injector, Uterine
Device Classification:	Class II

Predicate Devices:
The predicate device for the Intrauterine Access Balloon (IAB) Catheter is the Advanced Catheter for SHG and SIS cleared under K123258 by Catheter Research Inc.

The predicate device for the Selective Salpingography (SSG) Catheter is the Fallopian Tube Catheterization Set cleared under K171604 by Cook Incorporated.

Device Description:
The IAB and SSG Catheters facilitate access to the uterus and tubal ostium to deliver contrast media during diagnostic procedures.

The IAB Catheter is 9 French (Fr) in diameter and has a 23 cm working length. It is designed with a polyurethane shaft and a silicone distal balloon with a 2-cc inflation volume. The catheter includes two lumens, one for balloon inflation and the other can be used to inject contrast medium into the uterus for hysterosalpingography (HSG) and as an access channel that accepts devices up to 6 Fr in diameter for use in assessing tubal patency. The Intrauterine Access Balloon Catheter is packaged with a shipping stylet and a 3 mL syringe that is used to inflate the balloon with sterile media.

The SSG Catheter is manufactured from braided polyethylene and is designed with an angled distal tip with a radiopaque tungsten band. The catheter is 5.5 Fr in diameter and has a 40 cm working length. The SSG Catheter is intended to be used through a dimensionally compatible access catheter (IAB Catheter) to gain access to the uterine cavity for a more selective visualization of the fallopian tubes when positioned at the tubal ostium.

Both devices are supplied sterile (ethylene oxide) and are intended for single-use only.

Indications for Use:
Intrauterine Access Balloon Catheter:

The Intrauterine Access Balloon Catheter is used for delivery of contrast medium into the uterine cavity during hysterosalpingography (HSG) for examination of the uterus and fallopian tubes, and evaluation of tubal patency. The catheter lumen accepts catheters up to 6.0 French in diameter to access the uterine cavity for assessment of tubal patency.

Selective Salpingography Catheter:

The Selective Salpingography Catheter is intended to be used through a uterine access device and positioned at the tubal ostium for injection of contrast medium for fluoroscopic evaluation of tubal patency.

Comparison to Predicate Devices:

IAB Catheter:

Device Characteristics	Subject Device K181770 – IAB Catheter	Predicate Device K123258 – Advance Catheter for HSG and SIS	Comparison
Indications for Use	The Intrauterine Access Balloon Catheter is used for delivery of contrast medium into the uterine cavity during hysterosalpingography (HSG) for examination of the uterus and fallopian tubes, and evaluation of tubal patency. The catheter lumen accepts catheters up to 6 French in diameter to access the uterine	The intended use of " the advance catheter for HSG and SIS" is for the delivery of contrast media or saline during hysterosalpingogram (HSG) and saline infusion sonogysterography (SIS) into the female reproductive tract for examination of the uterus and/or fallopian tubes.	**Different:** The IAB Catheter and the predicate device are intended for injection of contrast media for HSG to evaluate the female reproductive tract. The predicate device can also be used for SIS procedures, which the subject device is not. This difference represents a more limited use of the device for only HSG procedures and does not impact the

Device Characteristics	Subject Device K181770 – IAB Catheter	Predicate Device K123258 – Advance Catheter for HSG and SIS	Comparison
	cavity for assessment of tubal patency.	The following are some clinical indications: suspected polyps, fibroids, adhesions, or endometrial thickening, and/or selective evaluation of fallopian tube patency. The advance catheter for HSG and SIS will be available in 5f size for patients with a nulliparous cervix and 7f size for patients with a multiparous cervix.	overall intended use of the device. The IAB Catheter is also indicated for introduction of catheters used to assess tubal patency through its lumen. The ability to pass a second catheter through the IAB Catheter does not represent a new intended use as the overall use is the same (assessment of patency/structural anomalies in the uterus and fallopian tubes).
General Design	Dual lumen catheter with an inflatable balloon at its distal tip for sealing the cervix. The catheter has two connection lines, one with a check valve for balloon inflation and another with a stopcock for contrast media infusion. The same lumen used for contrast medium infusion can also be used as an access port for up to 6 Fr devices used to assess tubal patency.	Dual lumen catheter with an inflatable balloon at distal tip for sealing the cervix. The catheter has two connection lines, one with a stopcock for balloon inflation and another with a Leur lock for contrast media/saline infusion. Device also has an introduction sheath that aids passage of the HSG/SIS catheter into the uterus.	**Different:** The predicate includes an additional introduction sheath to aid in delivery of the HSG/SIS catheter to the uterine cavity. The subject device does not include an introduction sheath, which is not needed to access the uterine cavity. This difference does not raise different S&E questions. The subject device can be used for passage of dimensionally compatible catheters into the uterine cavity that are used to assess tubal patency, which is not a feature of the predicate device. This additional use does not raise

Device Characteristics	Subject Device K181770 – IAB Catheter	Predicate Device K123258 – Advance Catheter for HSG and SIS	Comparison
			different S&E questions as compared to the predicate device (e.g., perforation risk, inability of device to assess uterine/tubal anomalies, etc.).
Materials	Polyurethane Acetal Polycarbonate HDPE Vinyl tubing Silicone	Specific materials unknown	**Different:** Materials used in the predicate device are not known. Material differences in these catheters do not raise different questions of S&E (e.g., biocompatibility, mechanical performance, etc.).
Catheter Length	23 cm	Length unknown	**Different:** The length of the predicate device is not known. Differences in length of devices do not raise is different questions of S&E. Note that other cleared devices have comparable lengths.
Catheter Diameter	9 Fr	5 Fr and 7 Fr	**Different:** The subject device has a larger diameter than the predicate device. This difference does not raise different questions of S&E. Note that other cleared devices have comparable or larger diameters.
Cervix Sealing Balloon	Yes	Same	Same

As shown above, the indications for use of the subject IAB Catheter is not identical to the predicate device; however, the differences do not represent a new intended use as both devices

are used to deliver contrast medium for the assessment of patency/structural anomalies in the uterus and fallopian tubes.

Regarding technological characteristics, the subject and predicate devices have similarities in their general designs. However, differences do exist as described in the table above (e.g., dimensions, materials, etc.). The differences identified do not raise different questions of safety and effectiveness as compared to the predicate device as stated in the table.

SSG Catheter:

Device Characteristics	Subject Device K181770 – SSG Catheter	Predicate Device K171604 – Fallopian Tube Catheterization Set	Comparison
Indications for Use	The Selective Salpingography Catheter is intended to be used through a uterine access device and positioned at the tubal ostium for injection of contrast medium for fluoroscopic evaluation of tubal patency.	The Fallopian Tube Catheterization Set is intended to be used through a uterine access device for fluoroscopic selective catheterization of the proximal fallopian tube(s) and injection of contrast medium in the evaluation of tubal patency.	**Different:** The subject and predicate indications are comparable with the exception that the subject device is only used to access the tubal ostium, while the predicate can be used for selective catheterization of the fallopian tubes. This difference represents a more limited use of the subject device, but does not impact the overall intended use of the device (assessment of tubal patency).
General Design	Catheter with a curved tip and a radiopaque band for visualization. It also includes a Luer connection for installation of contrast media. A dimensionally appropriate wire guide may be used to aid placement of the catheter.	The predicate device includes a Torque Control Catheter, an injection catheter, and three wire guides. The Torque Control Catheter is comparable to the subject device. It consists of a catheter with a curved tip and a Luer connection for installation of contrast media.	**Different:** The predicate device includes additional components needed to complete catheterization of the proximal fallopian tubes. The design of the subject device and the Torque Control Catheter are comparable and are both used to access the tubal ostium to assess tubal patency.

Device Characteristics	Subject Device K181770 – SSG Catheter	Predicate Device K171604 – Fallopian Tube Catheterization Set	Comparison
			These differences do not raise different questions of S&E.
Materials	Polyethylene Stainless Steel Rhenium-tungsten radiopaque band	Torque Control Catheter: Polyethylene Stainless Steel	**Different:** Materials used in the subject and predicate devices are the same except for the marker band on the subject device. This difference does not raise different questions of S&E.
Catheter Length	40 cm	50 cm	**Different:** The predicate is 10 cm longer than the subject device. The difference in length does not raise different questions of S&E as the length of this catheter only needs to be long enough to pass through a dimensionally acceptable uterine access catheter and have sufficient length to reach the tubal ostium.
Catheter Diameter	5.5 Fr	Same	**Same**

As shown above, the indications for use of the subject SSG Catheter is not identical to the predicate device; however, the differences do not represent a new intended use as both devices are used to deliver contrast medium for the assessment of patency of the fallopian tubes.

Regarding technological characteristics, the subject and predicate devices have similarities in their general designs. However, differences do exist as described in the table above (e.g., dimensions, materials, additional components, etc.). The differences identified do not raise different questions of safety and effectiveness as compared to the predicate device as stated in the table.

Performance Data:
The following tests have been conducted to ensure reliable design and performance under the specified testing parameters. These tests include:

- Sterilization validation testing per ISO 11135-1:2014

- Ethylene oxide residual testing per ISO 10993-7:2008(R)2012

- Transportation simulation testing per ASTM D4169-16

- Package integrity testing after real-time aging to three years:
    - Dye penetration testing per ASTM F1929-15
    - Seal strength testing per ASTM F88/F88M-15

- Biocompatibility studies, as follows:
    - Cytotoxicity testing per ISO 10993-5:2009
    - Guinea pig maximization sensitization testing per ISO 10993-10:2010
    - Intracutaneous irritation testing per ISO 10993-10:2010

- Bench Performance studies for the IAB Catheter before and after aging demonstrated that all predetermined acceptance criteria were met in the following tests and support a shelf-life of two years:
    - Compatibility testing – The set components to be used together as stated in the instructions for use were tested for dimensional compatibility. The same testing was completed to assure the compatibility of the SSG Catheter with the IAB Catheter.
    - Tensile testing – Tensile testing was completed for the different junctions of the device. Testing demonstrated that that the peak load value was greater than the predetermined acceptance criterion.
    - Lumen patency – Lumen patency of the device was completed via injection of media. Testing demonstrated that the IAB Catheter lumen was patent and the predetermined acceptance criteria were met.
    - Balloon leakage and integrity – The balloon was tested for leakage and integrity under the conditions of expected use. Testing demonstrated that the devices met the predetermined acceptance criteria for integrity and did not display leakage.
    - Balloon burst – The balloon was tested for burst volume. Testing demonstrated that the predetermined acceptance criteria were met and the balloon burst above the labeled volume.
    - Dimensional testing – Testing was completed to verify the devices critical dimensions (working length, length of side arm adapters, catheter outer diameter). Testing demonstrated that the acceptance criteria were met.
    - Check-Flo valve leak reduction – The Check-Flo valve was tested to show a reduction in leakage under conditions of expected use. Testing demonstrated that the device met the predetermined acceptance criteria for leakage reduction.

- Bench Performance studies for the SSG Catheter before and after aging demonstrated that all predetermined acceptance criteria were met in the following tests and support a shelf-life of three years:
    - The SSG Catheter was tested to assure dimensional compatibility with the IAB Catheter when used according to its intended use. Dimensional

compatibility was also assessed to support use with 0.039 inch diameter wire guides.

- Tensile testing – Tensile testing was completed for the different junctions of the device. Testing demonstrated that that the peak load value was greater than the predetermined acceptance criteria.
- Lumen patency - Lumen patency of the device was completed via injection of media. Testing demonstrated that the SSG Catheter lumen was patent and the predetermined acceptance criteria were met.
- Torque response – The catheter was tested for adequate torque response. Acceptance criterion was determined by Cook's internal procedures. Testing demonstrated that the acceptance criterion was met.
- Radiopacity of marker band – Testing demonstrated that the subject device was determined to be radiopaque in a simulated clinical setting.
- Kink radius – A characterization study was completed to find the kink radius for the SSG Catheter tip. Testing adequately characterized the kink radius.
- Dimensional testing – Testing was completed to verify the SSG Catheter critical dimensions (working length, catheter outer diameter). Testing demonstrated that the acceptance criteria were met.

Conclusion:

The results of the performance testing described above demonstrates that the subject devices are as safe and effective as the predicate devices and supports a determination of substantial equivalence.