October 26, 2018

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

Re: K180300
Trade/Device Name: Margolin HSG Cannula, Goldstein Sonohysterography Catheter
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: LKF
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)*
K180300

Device Name
Margolin HSG Cannula
Goldstein Sonohysterography Catheter

Indications for Use *(Describe)*

The Margolin HSG Cannula is for the delivery of contrast media or saline into the uterine cavity during Hysterosalpingography (HSG) or Sonohysterography (SHG) for examination of the uterus and fallopian tubes. When used for HSG, the Margolin HSG Cannula can be used for evaluation of tubal patency.

The Goldstein Sonohysterography Catheter is used to access the uterine cavity for the delivery of saline for Sonohysterography (SHG).

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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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

Margolin HSG Cannula
Goldstein Sonohysterography Catheter

Date Prepared: October 26, 2018

Submitted By:

Applicant:	Cook Incorporated
Contact:	Naomi Funkhouser, Rohini Patel
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:	Margolin HSG Cannula Goldstein Sonohysterography Catheter
Common Name:	HSG, SHG Catheters
Regulation Number:	21 CFR §884.4530
Regulation Name:	Obstetric-gynecologic specialized manual instrument
Classification Product Code:	LKF – Cannula, Manipulator/Injector, Uterine
Device Classification:	Class II

Predicate Devices:
K083594 – Foam Seal Catheter from OBG Products

The predicate device has not been subjected to a design-related recall.

Device Description:

The Margolin HSG Cannula and Goldstein Sonohysterography Catheter are single lumen uterine catheters that facilitate access to the uterus to deliver fluid (contrast media or saline) during diagnostic procedures. Both feature a silicone “acorn” wedge that seals the cervical canal and maintains the position of the catheter during the procedure.

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Margolin HSG Cannula

The Margolin HSG Cannula is comprised of a cannula and stylet. The cannula is made of polyurethane with a stationary silicone wedge at the distal end that maintains the position of the catheter in the external cervical os and 9.0 French tip which is approximately 2 cm in length. The wedge, characterized by an acorn shape features two 180° opposed sideports. The proximal end of the cannula is designed with a female luer lock-style adaptor. The Margolin HSG Cannula is provided with a stainless-steel stylet. The stylet is designed with a female luer lock-style plug proximal fitting. The Margolin HSG Cannula is 25 cm in length, is supplied sterile (ethylene oxide), and intended for one-time use.

Goldstein Sonohysterography Catheter

The Goldstein Sonohysterography Catheter includes four versions that range in size from 5.2 to 5.4 French. The 5.2 French catheters are made of polytetrafluoroethylene tubing and the 5.3 and 5.4 French catheters are made of polyethylene tubing. The 5.4 French catheter is designed with an additional polyurethane support sheath over the proximal portion of the catheter shaft to provide additional stiffness. A repositionable silicone acorn wedge is placed on the catheter shaft proximal to an ink band that is 7 cm from the distal tip of the catheter. The silicone acorn maintains placement of the catheter against the external cervical os, and a luer lock-style adapter is available for compatibility with luer lock syringes. The Goldstein Sonohysterography Catheter is 26 to 36 cm in length, supplied sterile (ethylene oxide), and intended for one-time use. Additional information on the different device versions is provided below:

- J-GSHC-522620 – 5.2 French and 26 cm long
- J-GSHC-523620 – 5.2 French and 36 cm long
- J-GSHC-532600 – 5.3 French and 26 cm long
- J-GSHC-542600-SV – 5.4 French and 26 cm long

Indications for Use:

- The Margolin HSG Cannula is for the delivery of contrast media or saline into the uterine cavity during Hysterosalpingography (HSG) or Sonohysterography (SHG) for examination of the uterus and fallopian tubes. When used for HSG, the Margolin HSG Cannula can be used for evaluation of tubal patency.
- The Goldstein Sonohysterography Catheter is used to access the uterine cavity for the delivery of saline for Sonohysterography (SHG).

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Comparison to Predicate Device:

The following table compares the Margolin HSG Cannula and Goldstein Sonohysterography Catheter to the predicate device:

Device Characteristics	Subject Device (K180300) Margolin	Subject Device (K180300) Goldstein	K083594 – The Foam Seal SIS/HSG Catheter	Comparison
Indication for Use	The Margolin HSG Cannula is for the delivery of contrast media or saline into the uterine cavity during Hysterosalpingography (HSG) or Sonohysterography (SHG) for examination of the uterus and fallopian tubes. When used for HSG, the Margolin HSG Cannula can be used for evaluation of tubal patency.	The Goldstein Sonohysterography Catheter is used to access the uterine cavity for the delivery of saline for Sonohysterography (SHG).	The Foam Seal SIS/HSG Catheter is intended for introduction of liquid into the uterine cavity for ultrasonogram and radiology procedure of the uterus and fallopian tubes.	Same intended use: Both devices are intended for use in delivery of contrast medium or saline to the uterine cavity for HSG and SHG procedures
Catheter Material	Polyurethane	Polyethylene or Teflon	Unspecified plastic	Different: The catheter material is not known for the predicate device. Differences in device materials between the subject and predicate device do not raise different questions of safety and effectiveness (S&E).
Positioner/Cervical Seal	Yes	Yes	Yes	Same
Positioner/Cervical Seal Material	Silicone	Silicone	Unspecified Foam	Different: The positioner/seal material is not known for the predicate device. Differences in device materials between the subject and predicate device do not raise different questions of S&E.
Catheter Length	25 cm	26 cm to 36 cm	37 cm	Different: The subject devices are shorter than the predicate device.

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				This difference does not raise different questions of S&E.
Tip Size	8.76 Fr	5.2 Fr to 5.4 Fr	1.6mm to 3 mm (4.8 Fr to 9.0 Fr)	Different: Tip sizes are different between the subject and predicate devices. These differences do not raise different questions of S&E.
Distal Tip Configuration	19-guage dual oval side ports, closed ended.	3 mm single side port, closed ended	open ended	Different: Differences in placement of fluid outflow openings in the tip of the subject and predicate devices do not raise different questions of S&E.

As shown above, the indication for use of the subject devices, Margolin HSG Cannula and the Goldstein Sonohysterography Catheter, as compared to the predicate device, the Foam Seal Catheter (K083594), is not identical; however, the differences do not alter the intended use of the devices, which are the same (i.e., delivery of contrast medium or saline to the uterine cavity for HSG and SHG procedures).

Regarding technological characteristics, the subject and predicate devices are similar in general design. However, differences do exist as described in the table above (e.g., dimensions, materials, tip configuration, 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 were performed to demonstrate that the Margolin HSG Cannula and Goldstein Sonohysterography Catheter met applicable design and performance requirements. All predetermined acceptance specifications were met in the following tests:

- **Sterilization Validation testing per ISO 11135-1:2007**
- **Transportation Simulation study per ASTM D4169-16**
- **Package Integrity testing after aging to three years:**
  - Bubble Leak test per ASTM F2096-11
  - Seal Strength testing per ASTM F88-09
  - Visual Inspection per ASTM F1866-09

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- **Biocompatibility studies, as follows:**
  - Cytotoxicity per ISO 10993-5:2009
  - Sensitization per ISO 10993-10:2010
  - Irritation per ISO 10993-10:2010
- **Performance studies before and after aging to three years. The testing below was conducted on the Margolin HSG Cannula and the Goldstein Sonohysterography Catheter unless stated otherwise:**
  - **Dimensional Verification:** Testing verified that the catheter, stylet, ink marker bands and silicone positioner dimensions are in conformance with Cook's predetermined acceptance specifications.
  - **Lumen Patency and Liquid Leakage Test:** Testing demonstrated that the fluid path of the catheter was patent and did not leak from any joints parts when tested with a predetermined injection pressure.
  - **Tensile Testing (hub to shaft [both devices], hub to stylet wire [Margolin HSG Cannula], and tip to shaft [Margolin HSG Cannula]):** Testing demonstrated that that the peak load value was greater than the predetermined acceptance specification.
  - **Positioner Force to Displace**: Testing was conducted to assess the force needed to displace the movable silicone positioner of the Goldstein Sonohysterography Catheter. In conformance to Cook requirements, the predetermined acceptance specification was met.
  - **Stylet Compatibility** - Testing was conducted to demonstrate that the stylet is compatible with the Margolin HSG Cannula (i.e., fits within the catheter lumen and does not extend beyond the tip of the catheter). In conformance to Cook requirements, the predetermined acceptance specification was met.

Conclusion:

The results of the performance testing described above demonstrates that the subject devices Margolin HSG Cannula and the Goldstein Sonohysterography Catheter are as safe and effective as the predicate device and supports a determination of substantial equivalence.