October 26, 2018

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

Re: K180291
Trade/Device Name: Cook® Silicone Balloon HSG Catheter
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: LKF
Dated: September 24, 2018
Received: September 25, 2018

Dear Yan Li:

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)*
K180291

Device Name
Cook® Silicone Balloon HSG Catheter

Indications for Use *(Describe)*
The Cook® Silicone Balloon HSG Catheter is used for delivery of contrast medium or saline into the uterine cavity and fallopian tubes for the evaluation of tubal patency using hysterosalpingography, or to access the uterine cavity for saline infusion sonohysterography.

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
Cook® Silicone Balloon HSG Catheter
Date Prepared: October 26, 2018

Submitted By:

Applicant:	Cook Incorporated
Contact:	Yan Li Rohini Patel
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone:	(812) 339-2235 x104987
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	Cook® Silicone Balloon HSG Catheter
Device Common Name:	HSG Catheter
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 Device:

uVue® HSG/SHG Catheter, Cook Incorporated, K160217

The predicate device has not been subject to any design-related recalls.

Device Description:

The Cook® Silicone Balloon HSG Catheter is a dual lumen polyurethane catheter that is manufactured in 5.0 or 7.0 French (Fr) sizes and is 30 cm in length. The Cook® Silicone Balloon HSG Catheter is available with an open-end tip, or a closed-end tip with a single side port. The silicone balloon is designed with a balloon volume of 1.0 mL (5.0 Fr) or 1.5 mL (7.0 Fr). Depending upon the device a 1 or 3 mL syringe is provided with the balloon catheter.

The Cook® Silicone Balloon HSG Catheter will be supplied sterile (ethylene oxide) and is intended for one-time use. The set is packaged in a peel-open pouch. The 5.0 Fr size catheter has a three-year shelf-life, and the 7.0 Fr size catheter has a two-year shelf-life.

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Indications for Use:

The Cook® Silicone Balloon HSG Catheter is used for delivery of contrast medium or saline into the uterine cavity and fallopian tubes for the evaluation of tubal patency using hysterosalpingography, or to access the uterine cavity for saline infusion sonohysterography.

Comparison to Predicate Device:

The following table compares the Cook® Silicone Balloon HSG Catheter to the predicate device:

Device Characteristics	**K180291 Cook® Silicone Balloon HSG Catheter**	**K160217 uVue® HSG/SHG Catheter**	**Comparison**
Indications for Use	The Cook® Silicone Balloon HSG Catheter is used for delivery of contrast medium or saline into the uterine cavity and fallopian tubes for the evaluation of tubal patency using hysterosalpingography, or to access the uterine cavity for saline infusion sonohysterography.	The uVue™ HSG/SHG Catheter is intended to access the uterine cavity for sonohysterography (SHG) and hysterosalpingography (HSG).	Same intended use: Both devices are intended for use in delivery of contrast medium or saline to the uterine cavity for HSG and sonohysterography procedures
Balloon Material	Silicone	Silicone	Same
Balloon Volume (mL)	5.0 Fr: 1 mL 7.0 Fr: 1.5 mL	1.5 mL	Different: The subject device includes a smaller diameter device version. This difference does not raise different questions of safety and effectiveness (S&E).
Catheter Tubing Material	Polyurethane	Polyurethane	Same
Catheter Tubing Outer Diameter (Fr)	5.0 and 7.0	6.2	Different: The subject device catheter diameters are smaller and larger than the predicate device. This difference does not raise different questions of S&E.
Length (cm)	30	26	Different: The subject device is longer than the predicate device. This difference does not raise different questions of S&E.
Lumen Number	2	3	Different: Both devices have two functional lumens for balloon inflation and contrast medium/saline infusion. The third lumen of the predicate device contains the internal

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Device Characteristics	K180291 Cook® Silicone Balloon HSG Catheter	K160217 uVue® HSG/SHG Catheter	Comparison
			stylet. This difference does not raise different questions of S&E.
Radiopaque Positioner	None	Yes	Different: The subject device does not include a positioner along the catheter shaft. This difference does not raise different questions of S&E.
Internal Stylet	None	Yes	Different: The subject device does not include an internal stylet in the catheter shaft. This difference does not raise different questions of S&E.
Accessory	1 or 3 mL syringe	3 mL syringe	Different: The 5 Fr device is supplied with a 1.0 mL syringe. The inclusion of a smaller syringe does not raise different questions of S&E.

As shown above, the subject and predicate device have the same intended use. In regards to technological characteristics, the subject and predicate device are similar in that they utilize comparable materials and are both supplied with syringes for inflation of the silicone balloons. However, differences do exist as described in the table above (e.g., dimensions, balloon volume, lumen number, lack of a stylet and positioner in the subject device, 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 testing was performed to demonstrate that the Cook® Silicone Balloon HSG Catheter met applicable design and performance requirements. All predetermined acceptance criteria were met in the following tests.

- **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 10993-10:2010
  - Intracutaneous Irritation testing per ISO 10993-10:2010
- **Transportation Simulation study per ASTM D4169-16**
- **Package Integrity testing after aging to two (7.0 Fr) or three (5.0 Fr) years:**
  - Bubble Leak test per ASTM F2096-11

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- Seal Strength testing per ASTM F88-09
- Visual Inspection per ASTM F1866-09

- **Bench Performance** studies before and after aging to two (7.0 Fr) or three (5.0 Fr) years demonstrated that all predetermined acceptance specifications were met in the following tests:
  - **Simulated Use:** Testing demonstrated that the catheter was able to be inserted through the cervical canal of a model of a nulliparous cervix, the syringe was able to mate with catheter check valve, inflate balloon to labeled volume, and deflate balloon fully.
  - **Balloon Integrity Test:** Testing demonstrated that the catheter and balloon did not show any abnormalities such as breakage, leakage, or cracking at the balloon joint or balloon material when filled to the labeled volume. It also demonstrated that the catheter and balloon did not leak after being filled to the labeled volume and submerging in a 37°C water bath for a minimum of 10 minutes.
  - **Balloon Diameter and Maximum Balloon Volume Testing:** Testing assessed the balloon diameter when filled with the maximum fill volume (i.e., 1.0 or 1.5 mL), and the maximum balloon pressure and volume at catastrophic failure of the test articles. Test results met the pre-defined acceptance specifications for these devices.
  - **Lumen Patency and Liquid Leakage Test:** Testing demonstrated that the fluid path of the catheter was patent and did not leak under a predetermined injection pressure.
  - **Tensile Testing (hub to shaft, shaft, shaft to manifold, extension tubing to manifold):** Testing demonstrated that that the peak load value was greater than the predetermined acceptance specification.

Conclusion:

The results of the performance testing described above demonstrates that the Cook® Silicone Balloon HSG Catheter is as safe and effective as the predicate device and supports a determination of substantial equivalence.