DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 6, 2016

Cook Incorporated
Kara Kanorr
Regulatory Affairs Specialist
750 Daniels Way, P.O. Box 489
Bloomington, IN 47404

Re: K160217
Trade/Device Name: uVue™ HSG/SHG Catheter
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKF
Dated: September 7, 2016
Received: September 8, 2016

Dear Kara Kanorr:

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 yours,

For Division

Douglas Silverstein -S
2016.10.06 16:06:16 -04'00'

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)*
K160217

Device Name
uVue™ HSG/SHG Catheter

Indications for Use *(Describe)*
The uVue™ HSG/SHG Catheter is intended to access the uterine cavity for sonohysterography (SHG) and hysterosalpingography (HSG).

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
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

Submitted By: Kara Kanorr
Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47404
Phone: (812) 339-2235 x104072
Fax: (812) 332-0281

Date Prepared: October 5, 2016

Device:

Submission:	Traditional 510(k) Premarket Notification, K160217
Trade Name:	uVue™ HSG/SHG Catheter
Common Name:	Intrauterine Catheter
Classification Regulation:	None
Classification Name:	None
Regulatory Class:	Unclassified
Product Code:	LKF (Cannula, Manipulator/Injector, Uterine)

Predicate Device:

The Advance Catheter for HSG and SIS, cleared under 510(k) K123258. This device has not been subject to a design-related recall.

Device Description:

The uVue™ HSG/SHG Catheter is a 6.2 French polyurethane catheter molded inside a 9.0 French polyurethane integrated catheter as a single piece. The device has a 26 centimeter working length. Along the distal end of the catheter, there is a silicone radiopaque positioner. In addition, distal from the positioner is a 1.5 milliliter silicone balloon. The catheter consists of three lumens: a closed lumen that contains a stainless steel stylet, an open lumen used to inflate the balloon, and an open lumen used to inject diagnostic media into the uterus. The catheter features a proximal fitting of a double lumen polyurethane hub with a polyethylene and polyetherimide stopcock attached. Both the hub and stopcock accept standard Luer lock or Luer slip syringes.

The purpose of the first luer is to allow for inflation of the balloon with saline via a proximally extending inflation line. The purpose of the second luer to allow for installation of diagnostic media into the uterine cavity. A 3 mL syringe will be provided with the catheter as a set.

The set will be supplied sterile and is intended for one-time use. The set is packaged in a Tyvek-polyethylene peel-open pouch with a two year shelf life.

Indications for Use:

The uVue™ HSG/SHG Catheter is intended to access the uterine cavity for sonohysterography (SHG) and hysterosalpingography (HSG).

Comparison to Predicate Devices:

The table below provides a detailed comparison of the subject and predicate device:

	Predicate Device	Subject Device
	The Advance Catheter for HSG and SIS (K123258)	**uVue HSG/SHG Catheter (K160217)**
Intended Use		
Indications for Use	Delivery of diagnostic contrast media or saline during hysterosalpingoram (HSG) and saline infusion sonohysterography (SIS) into the female reproductive tract for examination of the uterus and/or fallopian tubes.	The uVue™ HSG/SHG Catheter is intended to access the uterine cavity for sonohysterography (SHG) and hysterosalpingography (HSG)
Technology		
Size of catheter	5 and 7 Fr	6.2 Fr
Working length	28 cm	26 cm
Balloon size	1.5 ml	1.5 ml
Internal stylet	No	Yes
Tensile testing	Met performance testing requirements	Met performance testing requirements
Biocompatible	Yes	Yes
Sterile	Yes	Yes

The subject and predicate device have the same intended use – the delivery of contrast agents to the uterine cavity for HSG/SHG procedures.

The subject and predicate device have different technological characteristics, including different catheter sizes, working length, and the inclusion of an internal stylet. The different technological characteristics of the subject device do not raise different types of safety and effectiveness questions. All catheters must independently demonstrate they are biocompatible, sterile, and can maintiain their mechanical characteristics for their expected shelf life.

Performance Testing:

The following testing was performed in order to demonstrate that the uVue™ HSG/SHG Catheter met applicable design and performance requirements.

- Tensile Strength – Testing shows the tensile force during proper clinical use should not fracture the uVue™ HSG/SHG Catheter materials and bonds. The results showed that the predetermined acceptance criteria were met.

- 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.

- Balloon Integrity – Testing was performed with the requirement that the balloons should not burst or leak during nominal inflation and after a predetermined time period at nominal inflation in a water bath. The results showed that the predetermined acceptance criteria were met.

- Balloon Diameter and Maximum Balloon Volume – Testing was performed with the requirement that the balloons, subjected to a desired volume, should achieve a desired diameter while not having any rupture, leakage, or herniation of the entire balloon and/or catheter, or leakage at the hub during placement in a constant temperature bath. Upon achieving the desired diameter, testing continued until maximum burst volume. The results showed that the predetermined acceptance criteria were met.

- Balloon Deflation Reliability – Testing was performed with the requirement that the balloons subject to a desired volume and subsequently deflated, should achieve a desired diameter. The results showed that the predetermined acceptance criteria were met.

- Buckling Force – Characterization testing was performed to evaluate the buckling force of the distal length of the catheter. Results of the testing provided us with the peak load data.

- Stylet Puncture Force – Testing was performed to evaluate the force required to puncture the distal tip of the catheter and to confirm that it was greater than the buckling force. The results showed that the predetermined acceptance criteria were met.

- Biocompatibility – Testing demonstrated that the proposed device conforms with the biocompatibility requirements per ISO 10993-1:2009 *Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process* based on its intended use. The following biocompatibility tests were performed:

    - Cytotoxicity, per ISO 10993-5:2009 (Extraction Method)
    - Sensitiziation, per ISO 10993-10:2010 (Guinea Pig Maximization Sensitization)
    - Irritation, per ISO 10993-10:2010 (Intracutaneous Reactivity)

    All predetermined acceptance criteria were met.

- Shelf life – Testing demonstrated that the proposed device maintained conformed with the mechanical requirements described above and maintained sterility following aging for two years.

Conclusion:

The results of the testing described above demonstrates that the uVue™ HSG/SHG Catheter is as safe and effective as the predicate device and supports a determination of substantial equivalence.