February 15, 2018

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

Re: K171604
Trade/Device Name: Rösch-Thurmond Fallopian Tube Catheterization Set, Fallopian Tube Catheterization Set, and Fallopian Tube Catheterization Wire Guide with Platinum Tip
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: LKF
Dated: January 22, 2018
Received: January 23, 2018

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. 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,

Benjamin R. Fisher -S

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)*
K171604

Device Name
Rösch Thurmond Fallopian Tube Catheterization Set, Fallopian Tube Catheterization Set, and Fallopian Tube Catheterization Wire Guide with Platinum Tip

Indications for Use *(Describe)*
The Rösch Thurmond Fallopian Tube Catheterization Set is intended to be used for 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.

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.

The Fallopian Tube Catheterization Wire Guide with Platinum Tip is to be used through a dimensionally compatible (>0.018 inch inner diameter) uterine access device or selective salpingography catheter to assist in the 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 – K171604

Submitted By: Ian Herrman
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Date Prepared:	05/31/2017
Submission:	Traditional 510(k) Premarket Notification
Trade/Device Name:	Rösch Thurmond Fallopian Tube Catheterization Set, Fallopian Tube Catheterization Set Fallopian Tube Catheterization Wire Guide with Platinum Tip
Common Name:	Salpingography Catheter
Classification Regulation:	21 CFR §884.4530
Product Code:	LKF, Cannula, Manipulator/Injector, Uterine
Classification Name:	Obstetric-gynecologic specialized manual instrument
Device Classification:	Class II
Classification Panel:	Obstetrics/Gynecology

Predicate Device:

The predicate device is the Rösch-Thurmond Fallopian Tube Catheterization Set cleared under 510(k) K955508. This predicate device has not been subject to any design related recall.

Device Description:

This submission contains two catheter sets: the Rösch-Thurmond Fallopian Tube Catheterization Set and the Fallopian Tube Catheterization Set. The submission also includes the Fallopian Tube Catheterization Wire Guide with Platinum Tip, which is included in the Fallopian Tube Catheterization Set, and will also be sold separately.

<u>Rösch-Thurmond Fallopian Tube Catheterization Set</u>

This set contains a 31 cm, 9 Fr, Teflon introducing catheter; a 50 cm, 5.5 Fr, polyethylene, radiopaque, torque control catheter; and a 65 cm, 3 Fr, Teflon, radiopaque, injection catheter. The introducing catheter is designed with a check flow valve at the user end while the two other catheters have a standard luer lock adapter. The set also comes with three 90 cm long, stainless steel, accessory wire guides. Two of the wire guides are 0.035 inches in diameter and the other is 0.015 inches in diameter.

Fallopian Tube Catheterization Set

This set contains a 50 cm, 5.5 Fr, polyethylene, radiopaque torque control catheter, a 65 cm, 3.0 Fr nylon injection catheter with radiopaque tip, and two wire guides. The larger wire guide is stainless steel and has a diameter of 0.035 inches. The set also comes with a smaller wire guide which can be purchased in two variations; either the 0.015 inch diameter, 90 cm long, stainless steel Cope mandril wire guide, or the 0.018 inch diameter, 90 cm long, nitinol Cope mandril wire guide.

Fallopian Tube Catheterization Wire Guide with Platinum Tip

This wire guide is identical to the Nitinol Cope Mandril Wire Guide included in Fallopian Tube Catheterization Set, but can be purchased individually.

Both the Rösch-Thurmond Fallopian Tube Catheterization Set, the Fallopian Tube Catheterization Set, and the Fallopian Tube Catheterization Wire Guide with Platinum Tip are sterilized using ethylene oxide, packaged in Tyvek® polyethylene peel-open pouches, and have a shelf-life of three years. The devices are intended for one time use.

Indications for Use:

Rösch-Thurmond Fallopian Tube Catheterization Set:

> *The Rösch-Thurmond 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.*

Fallopian Tube Catheterization Set:

> *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.*

Fallopian Tube Catheterization Wire Guide with Platinum Tip:

> *The Fallopian Tube Catheterization Wire Guide with platinum tip is to be used through a dimensionally compatible (> 0.018 inch inner diameter) uterine access device or selective salpingography catheter to assist in the evaluation of tubal patency.*

Comparison to Predicate Device:

The predicate device is the Rösch-Thurmond Fallopian Tube Catheterization Set (K955508). The intended use for the predicate device is as follows:

> *The Rösch-Thurmond Fallopian Tube Catheterization Set is a fallopian tube catheterization set intended to be used through a Thurmond-Rösch Hysterocath® (K884291) or other uterine access device for fluoroscopic selective catheterization and cannulation of the proximal fallopian tube(s), followed by the introduction of contrast medium, in the evaluation of the tubal patency.*

This indication for use is identical to the indication for use in the subject device sets except it includes reference to a specific uterine access device and indicates for cannulation in addition to catheterization of the proximal fallopian tubes. The Fallopian Tube Catheterization Wire Guide with Platinum Tip is indicated to assist in the evaluation of tubal patency as indicated by both the predicate and subject device sets.

The differences between the predicate and the subject devices are listed below:

Rösch-Thurmond Fallopian Tube Catheter Set
(1) Wording in the indications for use

Fallopian Tube Catheterization (FTC) Set
(1) Wording in the indications for use
(2) The injection catheter for the FTC Set is made from Nylon instead of Teflon and has a radiopaque tip
(3) The wire guides included in the FTC Set vary slightly from those included in the predicate
(4) The FTC Set is not sold with an introduction catheter

As noted above the differences in the indications for use of the predicate and subject device sets do not raise any different questions of safety and effectiveness because subject device indications are within the intended use of the predicate device.

Though the nylon injection catheter included in the FTC Set is a different material and has a radiopaque tip, the material serves the same function as the Teflon in the predicate submission. Testing has been conducted to assure the nylon material performs as intended. The radiopaque tip provides visibility under fluoroscopy but as the Teflon

material was also visible under fluoroscopy there is no change to the procedure or safety and effectiveness.

The wire guides included with the Fallopian Tube Catheterization Set are slightly different from those included in the predicate. The 0.035 inch diameter Double Flexible Tip Safe-T-J® Wire Guide included in the FTC Set has a flexible tip on one end and a curved tip on the other. This effectively combines the functionality of both the straight safety wire guide and the curved tip 0.035 Safe-T-J® wire guide included in the predicate. The 0.035 inch diameter wire guides are made from the same materials. One variation of the FTC set comes with a 0.018 inch diameter Nitinol Cope Wire Guide which varies from the corresponding predicate wire guide in that it is nitinol instead of stainless and its diameter is 0.003 inches larger. The functionality and biocompatibility of the nitinol material has been tested and the results demonstrate that no different questions of safety and effectiveness were raised.

The FTC Sets are not sold with a 9 French introduction catheter because many physicians prefer to use a uterine access device with a smaller working channel which makes this set component unnecessary.

The subject devices have similar indications for use, methods of operation, and fundamental technological characteristics as the predicate device. Modifications to the subject devices from the predicate device are supported by testing and raise no different questions of safety and effectiveness.

Test Data:
The following testing was performed to demonstrate that Rösch-Thurmond Fallopian Tube Catheterization Set and the Fallopian Tube Catheterization Set met applicable design and performance requirements.

- 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 real-time aging:

  - Bubble Leak test per ASTM F2096-04
  - Seal Strength testing per ASTM F88-09
  - Visual Inspection: No package displayed damage (tears, folds, puncture holes, etc.)

- Bench Performance studies before and after aging demonstrated that all predetermined acceptance criteria were met in the following tests (No age testing was conducted for the wire guides, radiopacity, or tip deflection):

  - Compatibility Testing –The components in each set to be used together as stated in the instructions for use were tested for dimensional compatibility. The testing demonstrated compatibility between the components included in the sets being submitted.

  - Tensile Testing (catheters hub to shaft and tip to shaft) – Tensile testing was performed on the hub to shaft connection for each catheter and also on the tip to shaft section of the catheters that have a bonded tip. The acceptance criterion for these tensile tests was determined by Cook's internal procedures and according to Section 5.3 of JIS T 3246:2011. Testing demonstrated that that the peak load value was greater than the predetermined acceptance criterion.

  - Torque Response Testing (5.5 Fr catheter) – Torque control catheter was placed through its corresponding 9.0 French introducing catheter and the hub was rotated and the response of the distal tip was noted. Testing demonstrated that the torque-control catheter has an appropriate torque response per the predetermined acceptance criteria.

  - Liquid Leakage Test (5.5 Fr and 3 Fr catheters) – Liquid leakage testing was done on the catheters that will be used for the injection of contrast. The acceptance criterion was that the catheter assembly will not leak when an injection pressure of 38 kPa is applied. Testing demonstrated that fluid path catheter assembly did not leak under the predetermined injection pressure.

  - Corrosion Resistance (wire guide) – Representative testing was conducted according to Annex B of BS EN ISO 11070:2014 for each wire guide included in the subject device sets. Testing demonstrated that tensile

properties did not degrade after exposure of wires to corrosive conditions. The predetermined acceptance criterion was met.

- Fracture Testing (wire guide) – Representative testing was conducted for each wire guide included in the subject device sets. The fracture testing was performed according of Annex F of BS EN ISO 11070:2014 and an approved study protocol. The Testing demonstrated that no signs of fracture were observed in the region of interest, according to the predetermined acceptance criterion.

- Tensile Test (wire guide) – Representative testing was conducted according to Annex H of BS EN ISO 11070:2014 for each wire guide included in the subject device sets. Testing demonstrated that the peak load value was greater than or equal to the predetermined acceptance criterion.

- Resistance to Damage by Flex (wire guide) – Representative testing was conducted according to Annex G of BS EN ISO 11070:2014 for each wire guide included in the subject device sets. Testing demonstrated that there were no signs of defects or damage, when subjected to repeated flexing. The predetermined acceptance criterion was met.

- Radiopacity Evaluation – Testing demonstrated that the subject device was determined to be radiopaque in a simulated clinical setting.

- Tip Deflection Testing – Testing was conducted in order to compare the distal tip flexibility of the subject device to the predicate. Tested section included both the shaft material and bonded tip material of the subject device. Testing demonstrated that tip flexibility between the subject and predicate devices was comparable.

Conclusion:

In conclusion, the minor differences in indications for use statements between the subject and predicate devices do not alter the intended use of the subject device. The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness. The results of performance testing support that the Rösch-Thurmond Fallopian Tube Catheterization Set and the Fallopian Tube

Catheterization Set are as safe and effective as the predicate device. Therefore, the subject device is substantially equivalent to the predicate.