July 12, 2018

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

Re: K180552
Trade/Device Name: Modified Novy Cornual Cannulation Set
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: MOV
Dated: June 11, 2018
Received: June 12, 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. 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 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,

Michael T. Bailey -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)*
K180552

Device Name

Modified Novy Cornual Cannulation Set

Indications for Use *(Describe)*
The Modified Novy Cornual Cannulation Set is intended for use through the operating channel of a hysteroscope or other uterine access device, for hysteroscopic or fluoroscopic selective catheterization and cannulation of the proximal fallopian tube(s), followed by the introduction of chromotubation solution or contrast medium, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 – K180552

Modified Novy Cornual Cannulation Set
Date Prepared: July 12, 2018

Submitted By:

Applicant:	Cook Incorporated
Contact:	Naomi Funkhouser
	Rohini Patel
Applicant Address:	750 Daniels Way
	P.O. Box 489
	Bloomington, IN 47402
Contact Phone Number:	(812) 339-2235 x104371
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	Modified Novy Cornual Cannulation Set
Common Name:	Salpingography catheter
Regulation Name:	Obstetric-gynecologic specialized manual instrument
Regulation Number:	21 CFR §884.4530
Product Code:	MOV (catheters, salpingography)

Device Description:

The Modified Novy Cornual Cannulation Sets consist of an introducing catheter, an obturator, and an inner catheter with wire guide, a blue endoscopic septum cap, and two female Luer lock plugs. With this submission, Cook intends to offer two Novy Sets with curved introducing catheters.

Introducing catheters are 5.0 French in size. The curved introducing catheters measuring 35 centimeters or 40 centimeters in length are manufactured with Nylon Torcon with a bonded Non-radiopaque tip. Both Novy Set are supplied sterile and intended for one-time use.

Indication for Use:

The Modified Novy Cornual Cannulation Set is intended for use through the operating channel of a hysteroscope or other uterine access device, for hysteroscopic or fluoroscopic selective catheterization and cannulation of the proximal fallopian tube(s), followed by the introduction of chromotubation solution or contrast medium, in the evaluation of tubal patency.

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

Predicate Device:

The predicate device, the Novy Cornual Cannulation Set manufactured by Cook Incorporated (K931476), is a medical device set intended for use through the operating channel of a hysteroscope or other uterine access device, for hysteroscopic or fluoroscopic selective catheterization and cannulation of the proximal fallopian tube(s), followed by the introduction of chromotubation solution or contrast medium, in the evaluation of tubal patency. It is a group of sets including inner catheter with a wire guide, an introducing catheter, with obturator, and endoscopic cap, and female Luer lock caps. The predicate device was offered sterile for one-time use.

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

Comparison to Predicate Device:

The proposed Modified Novy Cornual Cannulation Set as compared to the predicate device, Novy Cornual Cannulation Set (K931476) has the same intended use, are identical in terms of intended use, principles of operation, basic technological characteristics, and nearly identical in dimension and design.

Regarding technological characteristics, whereas the predicate submission is offered in many dimensions, in the curved and straight options, the Modified Novy Cornual Cannulation Set, subject of this submission, offers only two curved options and two-dimensional options. The material of the curved tip of the introducing catheter was modified from Torcon *Polyethylene* tubing to a Torcon *Nylon* tubing. The minor modifications to the dimension of the inner catheter and the material change of the curved introducing catheter do not raise different questions of safety and effectiveness.

Summary of Performance Testing:

The following tests were performed to demonstrate that the dimensional modification to the inner catheter and the material modification of the tip of the curved introducing catheter have met applicable design and performance requirements to support a determination of substantial equivalence.

- Tensile Test of the Hub to Shaft joint – Verification that when subjected to maximum load requirements, the hub to shaft joint satisfies the minimum load requirement. The predetermined acceptance criterion was met.

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

- Tensile Test of the Tip to Shaft Joint – Verification that when subjected to maximum load requirements, the Tip to Shaft Joint satisfies the minimum load requirement. The predetermined acceptance criterion was met.
- Leak Test – Verification that the hub to shaft joint is free from leaks. The predetermined acceptance criterion was met.
- Dimensional Compatibility – Verification that the dimensions of the components of the Novy sets are clinically acceptable. The predetermined acceptance criteria were met.
- Component Compatibility – Verification that the device components are compatible with each other. The predetermined acceptance criteria were met.
- Biocompatibility - Testing shows that the subject device sets with short term mucosal membrane contact are non-cytotoxic, non-sensitizing, and non-irritating. The following tests were performed:
  - Cytotoxicity per ISO 10993-5:2009
  - Sensitization per ISO 10993-10:2010
  - Irritation per ISO 10993-10:2010
- Sterilization validation per ISO 11125:2014
- Shelf life - accelerated aging per ASTM F1980-02 to demonstrate that the subject device maintains the mechanical specifications and its packaging maintains sterility (see bullet below) after three years of aging. In conformance to Cook requirements, the predetermined acceptance criterion was met.
- Package integrity - per ASTM F1886-09 (visual inspection), ASTM F2096-11 (bubble leak), and ASTM F88-09 (seal strength). In conformance to Cook requirements, the predetermined acceptance criteria were met.

In conclusion, the results of these tests support a determination of substantial equivalence of the Modified Novy Cornual Cannulation Set to the predicate Novy Cornual Cannulation Set.