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K. 510(k) Summary

JUN 29 2006

Submitted by:

Cindy Rumple
Cook Urological, Incorporated and
Cook Ob/Gyn
1100 West Morgan Street
Spencer, Indiana 47460
March 31, 2006

Device:

Trade Name: Cook® Sonohysterography Biopsy Device

Proposed Classification Name: Endometrial Aspirator, Unclassified

Product Code: HHF, LKF

Regulation Number: 884.1060, Unclassified

Class: Class II

Predicate Devices:

The Cook® Sonohysterography Biopsy Catheter is comparable to existing predicate devices in distribution including the Tampa Catheter distributed by CooperSurgical, theEZ-HSG Catheter distributed by OBG Products, the Cook Hysterocath™ distributed by Cook Incorporated and Cook Ob/Gyn, the Goldstein Sonohysterography Catheter distributed by Cook Ob/Gyn. The biopsy function of the Cook® Sonohysterography Biopsy Catheter is similar to the Probet distributed by Gynetic Medical Products N.V., the Uterine Explora Model I distributed by Milex Products, the Wallace Suresample Endometrial Sampler distributed by Smiths Medical, the Pipelle de Cornier® Endometrial Suction Curette distributed by CooperSurgical, and the Aspiracath™ distributed by Cook Ob/Gyn.

Device Description:

The Cook® Sonohysterography Biopsy Catheter is used to access the uterine cavity for sonohysterography and to obtain endometrial biopsy, if indicated, utilizing the same device. The device is a single catheter designed to perform saline infusion sonohysterography then, if indicated, biopsy of the endometrium using the same device. The device will be supplied sterile and is intended for one time use. The materials used in the construction of the Cook® Sonohysterography Biopsy Device are well known in the medical field. Biocompatibility, Ethylene Oxide Residual, and Functional testing have shown that the materials and the device meet the test requirements and are safe and effective. Literary articles prove the usefulness of this type of device to the clinician and patient population.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program. The device will undergo packaging and sterilization procedures similar to devices currently marketed and distributed by Cook Urological, Incorporated and Cook Ob/Gyn. Being similar with respect to indications for use, materials, and physical construction to predicate devices, this device meets the requirements for section 510 (K) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 18, 2014

Cook Urological, Inc.
Cindy Rumple
Regulatory Affairs Technical Writer
1100 West Morgan Street
Spencer, IN 47460

Re: K060908
Trade/Device Name: Cook® Sonohysterography Biopsy Catheter
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: PGK, HFF
Dated (Date on orig SE ltr): March 31, 2006
Received (Date on orig SE ltr): April 3, 2006

Dear Cindy Rumple,

This letter corrects our substantially equivalent letter of June 29, 2006.

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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

Indications for Use

510(k) Number (if known): ~~Not Yet Assigned~~ K060908

Device Name: Cook® Sonohysterography Biopsy Catheter

Indications for Use: The Cook® Sonohysterography Biopsy Catheter is used to access the uterine cavity for sonohysterography and to obtain endometrial biopsy, if indicated, utilizing the same device. The device is a single catheter designed to perform saline infusion sonohysterography then, if indicated, biopsy of the endometrium using the same device. The device will be supplied sterile and is intended for one time use.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) OR Over the Counter Use____ (Part 21 CFR 807 Subpart C)

(Please do not write below this line-FDA use only-continue on another page if needed)

(Division Sign-Off)
Division of [illegible] Interventional, and Radiological Devices
510(k) Number K060908

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