K082939

510(k) SUMMARY

SEP - 3 2009

Submitted by:

Cindy Foote
Regulatory Affairs Specialist
Cook Urological, Incorporated
Cook Ob/Gyn
1100 West Morgan Street
Spencer, Indiana 47460
August 26, 2009

Device:
Trade Name: Cook® Fetal Membrane Manipulator

Proposed Classification Name: Instrument, Manual, Specialized, Obstetric-Gynecologic
21 CFR Part 884.4530
Class II, KNA

Predicate Devices:

The Cook® Fetal Membrane manipulator is intended to be used as an adjunct to a cerclage needle for replacement of fetal membranes and temporary occlusion of the internal cervical os during cervical cerclage. The device is used as an adjunct to a surgical needle such as the Deklene® Needle/Suture combination manufactured by Teleflex medical (needle is exempt, cervical needles are listed with FDA). The device is also equivalent to the ZUMI™ Zinnanti Uterine manipulator manufactured by CooperSurgical (K941458).

Device Description:

The Cook® Fetal Membrane Manipulator is used to atraumatically push and position emerging fetal membranes back through the cervical canal and into the uterus to facilitate a successful cervical cerclage procedure in order to prolong pregnancy to a successful delivery. The Cook® Fetal Membrane Manipulator is intended to be used as an adjunct to a cervical cerclage needle for replacement of fetal membranes and temporary occlusion of the internal cervical os during cervical cerclage. The Cook® Fetal Membrane Manipulator is a 12 French, 20-25 centimeter polycarbonate dual lumen catheter with a silicone balloon. The balloon catheter assembly includes a Check-Flo adapter. The device is provided sterile and intended for one-time use.

Substantial Equivalence:

The Cook® Cervical Ripening Balloon is comparable as an adjunct, with respect to intended use, to the published predicate device description and meets the requirements for 510(k) substantial equivalence.

Test Data:

Biocompatibility, sterility and performance testing were performed in accordance to Food and Drug Administration guidance's and recognized international standards. Testing results were well within the acceptance criteria. Testing data and information is included in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Cindy Foote
Regulatory Affairs Specialist
Cook Urological, Inc.
Cook Womens Health
750 Daniels Way
BLOOMINGTON IN 47404

SEP - 3 2009

Re: K082939
Trade/Device Name: Cook™ Fetal Membrane Manipulator
Regulation Number: 21 CFR §884.4530
Regulation Name: Instrument, Manual, Specialized Ob-Gyn
Regulatory Class: II
Product Code: KNA
Dated: August 24, 2009
Received: August 26, 2009

Dear Ms. Foote:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K082939

Indications for Use

510(k) Number (if known): K082939

Device Name: Cook® Fetal Membrane Manipulator

Indications for Use: The Cook® Fetal Membrane Manipulator is indicated as an adjunct to a cerclage needle for replacement of fetal membranes and temporary occlusion of the internal cervical os during cervical cerclage.

Prescription Use? X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colleen Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082939