Cook Incorporated
Cook® Cervical Ripening Balloon
510(k) Summary
21 CFR 807.92
Date Prepared: September 24, 2013

1. Submitter Information

Applicant:	Cook Incorporated
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2. Device Information

Trade Name:	Cook® Cervical Ripening Balloon
Common Name:	Catheter, Balloon, Dilation of the Cervical Canal
Classification:	Class II
Regulation:	21 CFR § 884.4260
Regulation Description:	Hygroscopic Laminaria cervical dilator
Product Code:	PFJ

3. Predicate Devices

The Cook® Cervical Ripening Balloon is substantially equivalent to the Atad Pre-Induction Cervical Dilator (Atad Developments and Medical Services Ltd.) cleared January 18, 2005 under 510(k) number K040625.

4. Comparison to Predicates:

The intended use and technological characteristics of the Cook® Cervical Ripening Balloon are substantially equivalent to the intended use and technological characteristics of the Atad Pre-Induction Cervical Dilator.

5. Device Description

The Cook® Cervical Ripening Balloon is a double-balloon catheter designed to mechanically ripen the cervix prior to labor induction at term when the cervix is unfavorable for induction. The tip of the Cook® Cervical Ripening Balloon is placed through the vagina and the cervical canal into the uterus. The distal balloon is positioned against the internal cervical os and inflated with up to 80 mL of saline; the proximal balloon is positioned against the external cervical os and also inflated with up to 80 mL of saline. The Cook® Cervical Ripening Balloon provides gradual mechanical cervical dilation by simultaneously providing pressure on the internal and external cervical os.

In addition to the standard version, the Cook® Cervical Ripening Balloon is also available with a removable stylet to add rigidity to the catheter and aid in placement of the balloon through the cervix. The stylet runs the length of the catheter shaft of the Cook® Cervical Ripening Balloon in a separate lumen that is closed at the distal tip. The user removes the stylet from the device once the distal uterine balloon is above the level of the internal cervical os.

6. Intended Use

The Cook® Cervical Ripening Balloon is indicated for mechanical dilation of the cervical canal prior to labor induction at term when the cervix is unfavorable for induction.

7. Technological Characteristics

The Cook® Cervical Ripening Balloon consists of an 18 Fr., 40 cm silicone catheter with a silicone tip and two silicone balloons, each inflatable up to 80 mL. Each balloon is inflated via a separate inflation lumen through a check valve at the proximal end of the

device. The check valves are marked with a "U" for the distal, uterine balloon and a "V" for the proximal, vaginal balloon.

For the Cook® Cervical Ripening Balloon with Stylet, a 46 cm malleable stainless steel stylet with an adjustable handle is included. The stylet is placed through a separate third lumen that is closed at the distal tip and marked at the proximal end with an "S." The stylet handle allows the user to adjust the stylet so that the distal tip is advanced to the distal (closed) end of the lumen.

The Cook® Cervical Ripening Balloon may be left indwelling for up to 12 hours. The Cook® Cervical Ripening Balloon is supplied sterile and is intended for one-time use.

To demonstrate reliable design and performance of the Cook® Cervical Ripening Balloon the following verification testing and information is presented:

- Balloon Deflation Reliability – Testing to demonstrate that the balloons deflate properly after use.
- Balloon Burst – Testing to demonstrate that the balloons do not burst at the maximum recommended inflation volume under simulated use conditions.
- Balloon Volume Maintenance – Testing to demonstrate that the balloons do not leak.
- Balloon Integrity – Testing to demonstrate that the balloons do not rupture under simulated use conditions.
- Balloon Response to Pullout – Testing to demonstrate that the distal balloon does not pull out from the patient under simulated use conditions.
- Catheter Tensile – Testing to demonstrate that the catheter shaft can sustain the maximum tensile forces anticipated in use.
- Biocompatibility – Testing to demonstrate that the device is biocompatible. The testing shows that the acceptance criteria from ISO 10993-1 were met.
- Simulated Use – Testing to demonstrate that the non-clinical users can properly follow the use instructions in a simulated environment.

In conclusion, the results of these tests provide reasonable assurance that the device is as safe and effective as the predicate and support a determination of 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

September 27, 2013

Cook, Inc.
% Chris Kilander, MS, RAC, CQE
Regulatory Affairs Manager
750 Daniels Way
Bloomington, IN 47404

Re: K131206
Trade/Device Name: Cook® Cervical Ripening Balloon
Regulation Number: 21 CFR§ 884.4260
Regulation Name: Hygroscopic Laminaria cervical dilator
Regulatory Class: II
Product Code: PFJ
Dated: August 29, 2013
Received: August 30, 2013

Dear Chris Kilander,

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 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/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,

Herbert P. Lerner -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

4. Indications for Use Statement

510(k) Number (if known): K131206

Device Name: Cook® Cervical Ripening Balloon

Indications for Use:

The Cook® Cervical Ripening Balloon is indicated for mechanical dilation of the cervical canal prior to labor induction at term when the cervix is unfavorable for induction.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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