DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 31, 2017

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

Re: K170622
Trade/Device Name: Bakri® Postpartum Balloon, Bakri® Postpartum Balloon with Rapid Instillation Components
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: OQY
Dated: February 28, 2017
Received: March 1, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Charles Viviano -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170622

Device Name
Bakri® Postpartum Balloon
Bakri® Postpartum Balloon with Rapid Instillation Components

Indications for Use *(Describe)*

Bakri® Postpartum Balloon is intended to provide temporary control or reduction of postpartum uterine bleeding when conservative management is warranted.

Bakri® Postpartum Balloon with Rapid Instillation Components is intended to provide temporary control or reduction of postpartum uterine bleeding when conservative management is warranted.

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.

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510(k) SUMMARY

Bakri® Postpartum Balloon with Rapid Instillation Components
21 CFR §884.4530
Date Prepared: March 29, 2017

Submitted By:

Applicant:	Cook Incorporated
Contact:	Naomi Funkhouser
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 Names:	**Bakri® Postpartum Balloon** **Bakri® Postpartum Balloon with Rapid Instillation Components**
Regulation Name:	Obstetrics-gynecology Specialized Manual Instrument
Classification Name:	Obstetrics/Gynecology
Regulation:	21 CFR §884.4530
Regulation Class:	II
Product Code:	OQY, Intrauterine Tamponade Balloon

Device Description:

The proposed devices are offered in two configurations, the Bakri Postpartum Balloon (henceforth referred to as Bakri) consisting of a double lumen silicone balloon catheter, a stopcock, and a 60 mL Luer-tip syringe and the Bakri Postpartum Balloon with Rapid Instillation Components (henceforth referred to as Bakri RI) configuration which additionally includes a dual check valve and polymer tubing. The tubing is fitted with a Luer lock-type connector to the dual check valve and a non-vented bag spike with a vented cap that connects to a saline bag (not included in the device).

The balloon catheter common to both configurations is designed as a dual lumen silicone shaft with 500 mL balloon. The proximal end of the catheter has a lighthouse adaptor designed to accept a drainage bag connector and a side arm which is fitted with a Luer Lock-type adaptor to

which a stopcock is attached and subsequently a Luer tip syringe or a dual check valve can be connected. The distal end of the catheter has two sideports spaced 180° opposite of each other, and the tip is rounded to a smooth finish. The polymer tubing of the Bakri RI rapid instillation components is 180 cm in length. Both the Bakri and the Bakri RI is supplied sterile and intended for one time use.

Indications for Use:

Bakri® Postpartum Balloon is intended to provide temporary control or reduction of postpartum uterine bleeding when conservative management is warranted.

Bakri® Postpartum Balloon with Rapid Instillation Components is intended to provide temporary control or reduction of postpartum uterine bleeding when conservative management is warranted.

Predicate Device:

The predicate device, the Bakri® Postpartum Balloon manufactured by Cook Incorporated (K062438), is a medical device intended to provide temporary control or reduction of postpartum uterine bleeding when conservative management is warranted. It is a tamponade balloon catheter constructed with silicone material and a 500 mL (max) balloon adhered to a dual lumen catheter used for drainage and balloon inflation. The device is sold with a stopcock and 60 mL syringe. The predicate device has not been subject to a design-related recall.

Comparison to Predicate Device:

The proposed Bakri and the balloon catheter of the Bakri RI as compared to the predicate device, Bakri Postpartum Balloon (K062438), are identical in terms of intended use, principles of operation, basic technological characteristics, materials of construction, and nearly identical in dimension and design. The Bakri RI includes Rapid Instillation Components which consist of a dual check valve and tubing. The Rapid Instillation components allow the physician fill the balloon without disconnecting and reconnecting the syringe at each reiteration of saline instillation into the balloon. The technological differences as a result of the changes to the balloon catheter and the addition of the rapid instillation components do not raise any different questions of safety and effectiveness.

Test Data:

The following tests were performed to demonstrate that the modifications to the balloon catheter of both the Bakri and Bakri RI and the addition of the rapid instillation component have met applicable design and performance requirements to support a determination of substantial equivalence. Biocompatibility testing was deemed unnecessary, since the materials used in the device are identical to the predicate, and all new materials do not directly or indirectly contact the patient.

- Inflated Balloon Reliability, Dimensional Evaluation, and Integrity –Verification that when subjected to maximum labeled volume, the inflated balloon and components of the proposed device do not show signs of leakage and/or rupture, and balloon dimensions meet the clinical and anatomical requirements.
- Tensile Test of the Distal Tip – Verification that when subjected to maximum load requirements, the distal tip satisfies the minimum load requirements.
- Sideport Drainage and Deflation Reliability– Verification that the proposed device will drain approximately 200 mL from the sideport in less than or equal to 1 minute and will have less than or equal to 30 mL of water left inside the balloon catheter after 15 minutes of drainage.
- Radial Pressure – Verification that the balloon can withstand a radial pressure of 100 mm Hg for up to 3 hours without leakage or rupture.
- Balloon Inflation Testing – Verification that the balloon can be inflated to the minimal volume of 500 mL with the Rapid Instillation Components.
- Simulated Use and Leak Test – Verification that the device performs as intended and does not leak during normal use.
- Tensile Testing – Verification that the Spike/Tubing, MLLA/Tubing, and Tubing withstands normal use forces.

In conclusion, the results of these tests support a determination of substantial equivalence of the balloon catheter common to the two configurations of the subject device to the predicate device.