October 28, 2022

Cook Incorporated
Ian Herrman
Senior Regulatory Affairs Specialist
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402

Re: K223098
Trade/Device Name: Bakri Essential Postpartum Balloon
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: OQY
Dated: September 29, 2022
Received: September 30, 2022

Dear Ian Herrman:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223098

Device Name
Bakri Essential Postpartum Balloon

Indications for Use *(Describe)*
The Bakri Essential Postpartum Balloon 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 Essential Postpartum Balloon

Submitted By

Applicant:	Cook Incorporated
Contact:	Ian Herman
Address:	750 Daniels Way P.O. Box 489 Bloomington, IN 47402
Contact Phone Number:	(812) 335-3575 x104034
Contact Fax Number:	(812) 332-0281
Date Prepared:	October 26, 2022

Device Information

Proprietary Name:	Bakri Essential Postpartum Balloon
Common Name:	Intrauterine tamponade balloon
Regulation Name:	Obstetric-Gynecologic Specialized Manual Instrument
Regulation Number:	21 CFR 884.4530
Regulation Class:	II
Product Code:	OQY, Intrauterine Tamponade Balloon

Predicate Device

Bakri Postpartum Balloon, manufactured by Cook Incorporated (K170622).

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

Device Description

The Bakri Essential Postpartum Balloon is composed of a double lumen silicone balloon catheter and a stopcock. The balloon catheter has a balloon with maximum inflation volume of 500 mL and a 24 Fr silicone shaft with an overall length of 58 cm, which includes the working length of 54 cm and proximal fittings. The shaft has two lumens, one designated for drainage, and the other for balloon inflation. The Bakri Essential is intended to provide temporary control or reduction of postpartum uterine bleeding when conservative management is warranted.

The Bakri Essential Postpartum Balloon is packaged in a Tyvek®/Polyethylene Peel-Open Pouch with five individually packaged and labeled products per marketing carton, is provided sterile, and is intended for one time use.

The Bakri Essential Postpartum Balloon is a modified version of the predicate device cleared under K170622.

Indications for Use

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

Comparison to Predicate Device

A comparison of the intended use and technological characteristics of the subject and predicate device are outlined in the table below.

General Device Characteristics	**Subject device K223098**	**Predicate device K170622**	**Comments**
Product code	OQY	OQY	Same
Intended use/Indications for Use	Bakri Essential Postpartum Balloon is intended to provide temporary control or reduction of postpartum uterine bleeding when conservative management is warranted	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 Component is intended to provide temporary control or reduction of postpartum uterine bleeding when conservative management is warranted.	Same.
Dimensions	Length: 58 cm (working length of 54 cm) Outer Diameter: 24 Fr Balloon Volume: 500 mL	Length: 58 cm (working length of 54 cm) Outer Diameter: 24 Fr Balloon Volume: 500 mL	Same
Materials	Balloon Catheter and Shaft: Silicone Female Luer-Lock Adapter: Polyamide	Balloon Catheter and Shaft: Silicone Female Luer-Lock Adapter: Polyamide	Same
Syringe	Syringe not included	60 mL syringe	Different
Stopcock	Included	Included	Same

Packaging	**Sterile Barrier**: Tyvek (1073B)/Polyethylene Peel Open Pouch Package. 5 individually packaged units per Box (8" & 1/8" X 2 & 3/8" X 17")	**Sterile barrier**: Tyvek (1059B)/Polyethylene Peel Open Pouch Package. 1 packaged unit per box (8" X 1 & 7/16" X 16") **Inner packaging**: Fitted in a PETG (Polyethylene Terephthalate Glycol-Modified tray with PETG retainer and seal	Different.
Sterilization	EO, 10^{-6}, single use	EO, 10^{-6}, single use	Same

The subject and predicate device have the same intended use, principles of operation, and technological characteristics. The only differences between the Bakri Essential and the predicate device are the packaging configuration and the removal of the syringe from the set. These differences do not raise different questions of safety and effectiveness and can be assessed by verification and validation testing.

Summary of Non-clinical Performance Testing

The support the proposed modifications to the subject device, design control activities and a risk analysis (depicting device change, risk associated, verification method, acceptance criteria and summary of results) according to ISO 14971:2019 was performed. The Bakri Essential Postpartum Balloon was subjected to applicable testing to assure reliable design and performance under the testing parameters. As the differences in the subject device compared to the predicate device include packaging differences and the removal of the syringe from the set, the following tests were conducted to ensure the reliability of the packaging at time zero and end of the three year shelf-life:

- Pouch Seal Strength Testing: verification that the minimum seal strength shall meet or exceed 1.2N per 15mm when tested in accordance with ASTM F88-15
- Bubble Leak Testing: verification that packaging shows no signs of cracks, pinholes, or imperfect seals indicated by bubbles, per ASTM F2096-11
- Dye Penetration Testing: verification that no packaging seal may be breached by dye per F1929-15
- Additional distribution testing followed by functional verification: verification that device shows no signs of damage after sterilization and simulation distribution.

Conclusion

The results of these testing described above demonstrate that the Bakri Essential Postpartum Balloon is as safe and effective as the predicate device and supports a determination of substantial equivalence.