August 28, 2020

Alydia Health
% Cindy Domecus, R.A.C.
Principal
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, CA 94010

Re: K201199
Trade/Device Name: Jada® System
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: OQY
Dated: July 27, 2020
Received: July 29, 2020

Dear Cindy Domecus:

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.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201199

Device Name
Jada® System

Indications for Use *(Describe)*
The Jada® System is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage 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 – K201199

I. SUBMITTER

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Date Prepared
August 28, 2020

II. DEVICE

Name of Device:	Jada® System
Common or Usual Name:	Vacuum-induced Hemorrhage Control
Regulation Name:	Obstetric-Gynecologic Specialized Manual Instrument
Regulation Number:	21 CFR § 884.4530
Regulatory Class:	II
Product Code:	OQY (Intrauterine Tamponade Balloon)

III. PREDICATE DEVICE

The predicate device is the Bakri® Postpartum Balloon, Bakri® Postpartum Balloon with Rapid Instillation Components, K170622. The predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Jada® System is a 41 cm long intrauterine device primarily made of silicone. The vacuum connector and seal valve are made of polyvinylchloride and acrylonitrile-butadiene-styrene. The device consists of an intrauterine loop on the distal end of a translucent tube. The proximal end of the tube has a vacuum connector for connection to a vacuum tube. Proximal to the connection of the Intrauterine Loop is

a donut-shaped cervical seal. The cervical seal is filled with and emptied of 60-120 mL of sterile fluid by attaching a syringe to the seal valve. The intrauterine loop has 20 vacuum pores oriented toward its inside diameter. The outer surface of the intrauterine loop is a silicone shield which overhangs the vacuum pores to protect tissue from vacuum and to prevent the vacuum pores from plugging with tissue and blood clots.

Before placing the Jada® System device inside the uterus, the intrauterine loop is compressed. The compressed loop is inserted into the uterus transvaginally. The cervical seal is placed within the vagina, at the external cervical os, and inflated. Vacuum is then applied to a maximum value of 90 mmHg until bleeding is controlled. The device should be fixed to the thigh along the tube.

V. INDICATIONS FOR USE

The Jada® System is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted.

VI. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Attribute	**K201199** **Subject Device:** **Jada® System**	**K170622** **Predicate Device:** **Bakri® Postpartum Balloon** **Bakri® Postpartum Balloon with Rapid Instillation Components**	**Comparison**
Manufacturer	Alydia Health	Cook Incorporated	N/A
Product Code	OQY	OQY	Same
Indications for Use	The Jada® System is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage 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	Different

		Instillation Components is intended to provide temporary control or reduction of postpartum uterine bleeding when conservative management is warranted.	
Principle of Action	Inserted into the uterus and establishes a vacuum to cause the uterine walls to press against one another, producing a tamponade of the bleeding vessels	Inserted into the uterus and is inflated to press outward on the uterine walls, producing tamponade of the bleeding vessels	Different
Design	Inflatable cervical seal and intrauterine loop with vacuum pore	Inflatable uterine balloon and a single drainage side port	Different
Rx/OTC	Rx	Rx	Same
Materials	Silicone, Polyvinylchloride (PVC), Acrylonitrile-Butadiene-Styrene (ABS)	Silicone	Different
Sterile	SAL 10^{-6}	SAL 10^{-6}	Same
Single-use	Yes	Yes	Same

The Indications for Use statement for the Jada® System is not identical to the predicate device; however, the differences do not alter the intended use of the device. Both the subject and predicate devices have the same intended use for the treatment of abnormal uterine bleeding when conservative management is warranted.

The following technological differences exist between the subject and predicate devices:

- Principle of Operation: The subject device utilizes vacuum to affect tamponade on uterine walls, whereas the predicate device utilizes the fluidic pressure of an expanding balloon to affect tamponade
- Design: The subject device's intrauterine loop has a looped (drain) tube with a series of Vacuum Pores on the inside surface. The intrauterine loop features an elliptical pattern that lays flat on the uterine tissue bed, whereas the

predicate device has a single opening drain tube protruding out of the middle of the inflated balloon
- Materials: The patient contacting portions of both devices are made of silicone. However, the subject device includes a seal valve and vacuum connector made of ABS and PVC, respectively. All patient contacting devices are made of silicone for the subject and predicate device.

These differences in technological characteristics do not raise different questions of safety and effectiveness. Non-clinical and clinical data provided by Alydia Health were used to address the differences related to design and principle of operation to demonstrate substantial equivalence to the predicate device.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Mechanical Testing
The following mechanical tests were performed:

- Cervical Seal and Tube Dimensions: Verification of tube and seal dimensions
- Intrauterine Loop Portion Dimensional Test – Verification of intrauterine loop dimensions
- Removal of Intrauterine Portion Test – Verification that intrauterine loop and shield remain intact during removal
- Vacuum Pore Diameter – Verification of vacuum pore size
- No Sharp Edges – Verification of smooth edges and surfaces of device
- Attaining Pressure Drop – Verification that cervical seal withstands pressure differential of 180 mmHg vacuum
- Static Load Test – Verification that the cervical seal withstands a static load of 1 lb. applied axially along the tube without failure
- Overfill Capacity – Verification that cervical seal does not fail when filled with 180 mL water.
- Cervical Seal Inflation – Verification that cervical seal can be filled with 60 mL of water within 30 seconds with 10 lbs. of force on syringe
- Impact Load Test – Verification that the cervical seal withstands an impact test of dropping a 1 lb. weight 2 ft axially along the tube without failure
- Connection Tube Junction Impact Load Test - Verification that the intrauterine loop withstands an impact test of dropping a 1 lb. weight 2 ft axially along the tube without failure
- Flow Rate – Verification that the device with vacuum is able to evacuate 400 mL of simulated blood in 1 minute or less
- Device Integrity Leak Test – Verification that the joints of the device do not leak when 180 mmHg of vacuum is applied

- Integration to Hospital Vacuum Line – Verification that the device connects to a vacuum tube
- Inflation Tube Geometry – Verification that the cervical seal inflation lumen is functional
- Syringe Accommodation – Verification that a luer tapered syringe can be attached to the seal valve
- Cervical Seal Deflation – Verification that cervical seal can be emptied of 60 mL of water within 30 seconds with 10 lbs. of force on syringe
- Cervical Seal Diameter and Bond Stability – Verification that the seal maintains a diameter of 70 mm and maintains integrity after 48 hours
- Clotted Blood Test – Verification that the device can evacuate simulated blood in the presence of clotted blood without occluding
- Vacuum Connector Bond Test – Verification that the vacuum connector withstands a tensile load of 8.8 lbf
- Seal Valve Bond Test – Verification that the seal valve withstands a tensile load of 3.7 lbf

Biocompatibility Testing

The Jada® System is a surface device in contact with a breached surface, with limited duration (≤ 24 hours).

The biocompatibility evaluation for the Jada® System was conducted in accordance with the FDA June 2016 guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff*. The battery of testing included the following tests:

- Cytotoxicity (ISO 10993-5:2009)
- Maximization Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-10:2010)
- Systemic toxicity (ISO 10993-11:2017)
- Material Mediated Pyrogenicity (ISO 10993-11:2017)

Sterilization and Shelf-Life Testing

The Jada® System is sterilized using gamma radiation to a SAL = 10^{-6}, according to ISO 11137-2: 2013. A shelf-life of 4 years has been established based on real-time aging.

Clinical Studies

Clinical testing of the Jada® System included an initial pilot study of 10 women in Indonesia, an initial phase of the pivotal study of 13 women in Uganda, and an IDE pivotal study of 107 women in the U.S. Substantial equivalence was based in part on the pivotal study, as described below.

Pivotal Study

The pivotal study was a prospective, multicenter, single-arm, open label, literature-controlled study at 12 sites in the U.S. A total of 107 subjects were enrolled into the study, of which 106 subjects were evaluable. Study entrance criteria included the following estimated blood loss (EBL) ranges:

Vaginal delivery: 500 – 1500 mL EBL or
C-section delivery: 1000 – 1500 mL EBL

Primary Effectiveness Endpoint

The primary effectiveness endpoint was as follows:
Control of postpartum hemorrhage, defined as the avoidance of non-surgical, second-line or surgical intervention to control uterine hemorrhage after the use of the Jada® System per the Instructions for Use.

Non-surgical, second line procedures include uterine balloon therapy, uterine packing, or uterine artery embolization. Surgical intervention includes procedures such as uterine arterial ligation, uterine compression sutures or hysterectomy.

Note: Continuation of the administration of uterotonics concomitant with and post Jada® System use is standard of care and does not constitute failure of the primary effectiveness endpoint.

Primary Safety Endpoint

The primary safety endpoint was the incidence, severity and seriousness of device-related adverse events.

Effectiveness Results

The analysis of effectiveness was based on the 106 subjects in the ITT Cohort. Results from the 104 subjects in the mITT and 97 subjects in the PP Cohort are also presented. The treatment success rate in the ITT Cohort was 94.3% (100/106, $p<0.001$), with a lower bound 95% confidence limit of 88.1%. The success rate performance goal was 82.0% (95% CI: 73.4% to 89.2%), based on a meta-analysis of data from literature assessing the performance of the Bakri Postpartum Balloon. The treatment success rate in the mITT Cohort was 96.2% (100/104; 95% CI: 90.4%, 98.9%). The treatment success rate in the PP Cohort was 99% (96/97; 95% CI: 94.4% to 100%).

Safety Results

There were no adverse events judged definitely related to the device or the procedure and there was a low rate of possibly related adverse events, all of which were anticipated in this patient population and with introduction of an intrauterine device. Five possibly device-related adverse events were rated as “mild” and three were rated as “moderate” without any event in this group rated “severe”. The three moderate events were cases of endometritis, which is a known risk of long labor, vaginal exam, and postpartum hemorrhage.

Summary
In summary, the pivotal trial of the Jada® System demonstrates the device's safety and effectiveness in the treatment of abnormal postpartum uterine bleeding and hemorrhage.

VIII. CONCLUSIONS

The nonclinical and clinical performance data described above demonstrate that the Jada® System is as safe and effective as the predicate device and supports a determination of substantial equivalence.