September 30, 2021

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

Re: K212757
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: August 30, 2021
Received: August 31, 2021

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.
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)*
K212757

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 – K212757

I. SUBMITTER

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Date Prepared September 29, 2021

II. DEVICE

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

III. PREDICATE DEVICE

The predicate device is the Jada System, K201199. This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The subject of this submission is the Jada System kit, which includes 1) the Jada System, 2) a commercially available pre-sterilized vacuum tubing, and 3) a commercially available pre-sterilized luer lock syringe.

The Jada System is a 41 cm long intrauterine device made of silicone. 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 the vacuum tubing. 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 luer lock syringe to the seal valve. The intrauterine loop consists of a loop tube with 21 vacuum pores oriented toward the inside diameter of the intrauterine loop. On the outer surface of the intrauterine loop is a 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 and filled with 60-120 mL of sterile fluid. The vacuum tubing is attached to the vacuum connector on the Jada System and vacuum is then applied to a maximum value of 90 mmHg until bleeding is controlled. The Jada System 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	**K212757 Subject Device: Jada System**	**K201199 Predicate Device: Jada System**	**Comparison**
Manufacturer	Alydia Health	Alydia Health	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.	The Jada System is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted.	Same
Mechanism 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 establishes a vacuum to cause the uterine walls to press against one another, producing a tamponade of the bleeding vessels.	Same
Design	Inflatable cervical seal and intrauterine loop with vacuum pores. The intrauterine loop tube vacuum pore count is increased from 20 to 21 and the seal valve features luer syringe attachment.	Inflatable cervical seal and intrauterine loop with vacuum pores. Seal Valve features the friction syringe attachment.	Different
Rx/OTC	Rx	Rx	Same
Materials	Silicone, polycarbonate, Acrylonitrile- Butadiene-Styrene (ABS)	Silicone, Polyvinylchloride (PVC), Acrylonitrile-Butadiene-Styrene (ABS)	Different
Sterile	SAL 10^{-6}	SAL 10^{-6}	Same
Single Use	Yes	Yes	Same

The subject and predicate device have identical indications for use statements and have the same intended use - the treatment of abnormal uterine bleeding when conservative management is warranted.

The subject Jada System is an updated version of the predicate Jada System with modifications to 1) improve manufacturability, 2) streamline packaging, and 3) improve user experience and aesthetics of the device. Following is a list of technological characteristics that remain the same between the subject and predicate devices:

- Vacuum induced collapse of the uterus causing the uterine walls to press against one another, producing tamponade of the bleeding vessels.
- Intrauterine loop to transmit vacuum to the uterine space.
- Drain pores within the intrauterine loop to evacuate blood, body fluids, and residual clots from the uterine space.
- Filled and expanded cervical seal to enable the maintenance of vacuum within the uterine space.
- Vacuum connector for attachment of vacuum tubing.
- Seal valve with automatic shut-off for filling the cervical seal.
- In-dwelling treatment within the uterus and genital tract ≤24 hours
- Drain tube to remove blood and fluid from postpartum uterus
- All patient contacting materials are silicone

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

- The seal valve on the subject device features a luer syringe attachment instead of the friction syringe attachment of the predicate device, to provide a more secure attachment of the syringe.
- The inflation lumen that is used to fill the cervical seal on the subject device has a larger cross-sectional area, to allow easier filling and removal of fluid from the Cervical Seal during use.
- The seal valve orientation of the subject device was changed from 12 o'clock to 9 o'clock/3 o'clock, to achieve a lower profile of the device in the device packaging.
- The seal valve body on the subject device was changed to clear polycarbonate from the white ABS (acrylonitrile butadiene styrene) of the predicate device. The polycarbonate valve enables a luer-lock syringe fitting with higher flow.
- The vacuum connector on the subject device was changed to white ABS from the clear PVC (polyvinyl chloride) of the predicate device, to improve the aesthetics of the device.
- The intrauterine loop tube vacuum pore count was increased from 20 to 21 on the subject device, to improve manufacturability.
- The sterile packaging of the subject device was changed to a Tyvek lidded tray from a pouch with a device backing card of the predicate device, to improve the appearance of the packaging, remove the complexity of the backing card and to achieve a smaller form factor for the sterilized unit.
- The subject device will be provided for the user in a kit carton that contains the Jada System, a commercially available pre-sterilized 60 mL syringe and a commercially available pre-sterilized 12' vacuum tubing for customer convenience.

These differences in technological characteristics do not raise different questions of safety and effectiveness and can be addressed through performance testing. Non-clinical data provided by Alydia Health were used to address the differences related to design and packaging to demonstrate substantial equivalence to the predicate device, as discussed in Section VII.

VII. PERFORMANCE DATA

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

Mechanical Testing

Mechanical testing on the subject Jada System was identical to the testing performed on the predicate Jada System. Specifically, the following mechanical tests were performed at baseline (T=0) and on aged samples (T=1 year):

- Cervical Seal and Tube Dimensions: Verification of tube and seal dimensions
- Intrauterine Loop Portion Dimensional Test – Verification of intrauterine loop dimensions
- 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 min 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 tubing
- 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 – Vacuum connector bond remains intact after a proof load of 8.8 lbf is applied
- Seal Valve Bond Test – Seal valve bond remains intact after a proof load of 3.7 lbf is applied

Packaging Testing

Testing of the kit packaging for the subject device consisted of transportation per ASTM-D4169-16 followed by gross leak detection per ASTM F2096-11 and for seal strength per ASTM F88/F88M-15. Furthermore, the Tyvek lidded tray of the subject Jada System was tested for aging (ASTM F1980-16) followed by packaging integrity testing for gross leak detection per ASTM F2096-11 and for seal strength per ASTM F88/F88M-15.

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 subject 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
- Maximization Sensitization

- Vaginal Irritation
- Systemic toxicity
- Material Mediated Pyrogenicity

Sterilization and Shelf-Life Testing

The subject and predicate Jada Systems are both sterilized using gamma radiation to a SAL of 10^{-6} according to ISO 11137-2: 2013. A shelf-life of 1 year has been established based on accelerated aging for the subject device.

VIII. CONCLUSIONS

The nonclinical 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.