May 15, 2026

Organon, LLC
Riddhish Patel
Associate Principle Scientist, Regulatory Affairs
30 Hudson St.
Floor 33
Jersey City, New Jersey 07302

Re: K253642
Trade/Device Name: Jada System (Jada-2002)
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: OQY
Dated: April 14, 2026
Received: April 15, 2026

Dear Riddhish Patel:

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 (the 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 available 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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253642

Device Name
Jada System (Jada-2002)

Indications for Use *(Describe)*
The Jada System (Jada-2002) 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary – K253642

I. SUBMITTER

Organon, LLC.
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Contact: Riddhish Patel,
Associate Principle Scientist, Regulatory Affairs
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Date Prepared: May 14, 2026

II. DEVICE

Name of Device:	Jada System (Jada-2002)
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 (Intrauterine Tamponade Balloon)

III. PREDICATE DEVICE

The predicate device is the Jada System, K212757. 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.

The Jada System convenience kit is packaged in a secondary cardboard carton. The packaging

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configuration consists of a) the Jada System, intrauterine device packaged in a sterile blister tray with Tyvek lid, b) a 60ml plastic luer lock syringe packaged in a sterile peelable pouch c) vacuum tubing packaged in a sterile peelable pouch and d) accompanying documentation.

The secondary carton and individual primary packs contain the required labelling information and symbols for communication to the end user based on international consensus standards.

The Jada System convenience kit is intended for single use (i.e., disposable) and has a three year shelf-life.

V. INDICATIONS FOR USE

The Jada System (Jada-2002) 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	**K253642 Subject Device: Jada System (Jada-2002)**	**K212757 Subject Device: Jada System**	**Comparison**
Manufacturer	Organon	Alydia Health	N/A
Product Code	OQY	OQY	Same
Indications for Use	The Jada System (Jada-2002) 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 21 vacuum pores. The seal valve features luer lock syringe attachment.	Inflatable cervical seal and intrauterine loop with 21 vacuum pores. The seal valve features luer lock syringe attachment.	Different*
Rx/OTC	Rx	Rx	Same
Materials	Silicone, polycarbonate, Acrylonitrile- Butadiene-Styrene (ABS)	Silicone, polycarbonate, Acrylonitrile- Butadiene-Styrene (ABS)	Same
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.

*Since the clearance of JADA system convenience kit under K212757, Organon has made several changes which individually or cumulatively did not require a submission of a new 510(k). These changes were

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assessed using the FDA guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device – Guidance for Industry and Food and Drug Administration Staff" issued October 25, 2017 and these changes are captured within the write up below as technological differences.

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

- The subject device may utilize silicones procured from an alternate supplier for the following device components: Drain Shield (Tube Shield), Bilumen Shaft (Bilumen Tube), Tubing Connector, Y-Connector.
- The subject device has kitted accessory components from alternate suppliers. The 60mL luer lock syringe and 12' suction vacuum tubing are off the shelf devices available on US market and are considered like for like alternate accessory devices for use with Jada System. The convenience kit performance specifications remain unchanged.
- Manufacturing related changes including qualification of alternate supplier of SLS mold release agent (production aid for ejecting silicon parts from the mold tooling during molding), and qualification of new replacement molds with additional cavities for increased production efficiency.

The differences in technological characteristics also do not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA

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

Non-clinical performance was leveraged from K212757.

Clinical Test Summary and Conclusions

Study data from the following study: RUBY – Treating abnormal postpartum uterine bleeding or postpartum hemorrhage with the Jada System was utilized to update device labeling to support the use of Jada System in pregnant patients who give birth at a gestational age of ≥ 28 weeks. This was a multicenter, observational, chart review study. This study was a post-market study of the Jada System in commercial distribution. Data was collected through the duration of the patient's admission for their delivery (i.e., starting with admission and continuing through discharge). Regular chart review occurred from the date the site began commercial use of the device (October 2020-March 2022). Sixteen sites participated in this study. Patients treated with the Jada System for abnormal postpartum uterine bleeding or PPH at these sites were included in the registry.

The data was collected from 800 patients. Among these 800 patients, 50 (6.3%) gave birth at < 34 weeks of gestation, including 36 at ≥ 28 and < 34 weeks of gestation (23 patients with Cesarean delivery, 13 patients with vaginal delivery). The primary effectiveness outcome was treatment success, defined as control of abnormal bleeding (> 500 mL) or postpartum hemorrhage (≥ 1000 mL) after device insertion with no treatment escalation or bleeding recurrence. Treatment success rates were 85.7% for preterm birth at less than 28 wGA (81.8% vaginal [9/11], 100% cesarean [3/3]). Treatment success rates were 88.9% for preterm births 28 to less than 34 wGA (100% vaginal [13/13], 82.6% cesarean [19/23]). Results were consistent with births greater than or equal to 34 weeks of gestation. Overall, the effectiveness was similar among patients who delivered between ≥ 28 and < 34 weeks of gestation, and those who delivered at ≥34 weeks of gestation as referenced in the warning section of current Jada System label, in both cesarean delivery and vaginal delivery. There was only 1 (4.3%) adverse event reported as severe and serious among the patients who delivered at between ≥ 28 and < 34 weeks of gestation. This unique adverse event was not reported as possibly or definitely related to the JADA System. Among the patients who delivered at ≥ 34 weeks of gestation, there were 37 (4.9%) adverse events(AE) reported (11 mild, 15 moderate and 11 severe), among which 32 (4.3%) were serious AE. Eight AE were reported as adverse device effects, and 3 AE were reported as serious adverse device effects.

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For both vaginal and Cesarean births in real-world settings, the Jada System provided rapid, effective, and safe control of bleeding. The adverse event profile and device related adverse events was consistent with that observed in the registrational PEARLE trial.

Conclusion

The overall effectiveness and safety of the Jada system among 28 < 34 weeks of gestation group is comparable to patients who delivered ≥ 34 weeks of gestation. This conclusion is based on a multicenter, observational, chart review, post-market study including 800 patients with abnormal postpartum bleeding treated with the Jada system, of which 786 were considered for this analysis (36 patients at 28 < 34 weeks of gestation, and 750 patients ≥ 34 weeks of gestation). Additionally, the overall effectiveness (treatment success rate defined as control of bleeding without escalation of treatment was 89.4% (95% CI: 87.0% to 91.5%)) and safety results of this real-world evidence study are similar with the results of the pivotal PEARLE study (overall effectiveness for the same endpoint was 94.3% (95% CI 88.1%-97.9%)) submitted for initial clearance of the Jada System.

References

Kara M. Rood, Angela Bianco, Joseph R. Biggio, Marcela C. Smid, Hyagriv N. Simhan, James Li, Candice Yong, Patricia I. Carney, Damien J. Croft & Dena Goffman (2025) Real-world use of a vacuum-induced hemorrhage-control device in births <34 weeks gestational age, The Journal of Maternal-Fetal & Neonatal Medicine, 38:1, 2451658, DOI: 10.1080/14767058.2025.2451658

D'Alton, Mary E. MD; Rood, Kara M. MD; Smid, Marcela C. MD; Simhan, Hyagriv N. MD, MS; Skupski, Daniel W. MD; Subramaniam, Akila MD; Gibson, Kelly S. MD; Rosen, Todd MD; Clark, Shannon M. MD; Dudley, Donald MD; Iqbal, Sara N. MD; Paglia, Michael J. MD, PhD; Duzyj, Christina M. MD, MPH; Chien, Edward K. MD; Gibbins, Karen J. MD; Wine, Kathryn D. MPH; Bentum, Nana Ama A. MD; Kominiarek, Michelle A. MD; Tuuli, Methodius G. MD; Goffman, Dena MD. Intrauterine Vacuum-Induced Hemorrhage-Control Device for Rapid Treatment of Postpartum Hemorrhage. Obstetrics & Gynecology 136(5):p 882-891, November 2020. | DOI: 10.1097/AOG.0000000000004138

VIII. CONCLUSIONS

The clinical performance data described above demonstrate that the Jada System (Jada-2002) is as safe and effective as the predicate device and supports a determination of substantial equivalence.

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