October 30, 2019

Ujenzi Charitable Trust
℅ Jonathan Kahan
Regulatory Counsel
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, D. C. 20004

Re: K191264
Trade/Device Name: Every Second Matters-Uterine Balloon Tamponade ("ESM-UBT")
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: OQY
Dated: September 30, 2019
Received: September 30, 2019

Dear Jonathan Kahan:

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,

Sharon M. Andrews
Acting 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)*
K191264

Device Name
Every Second Matters-Uterine Balloon Tamponade ("ESM-UBT")

Indications for Use *(Describe)*
The ESM-UBT device 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.

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510 (k) Summary – K191264

1. Submitter Information

Applicant: Ujenzi Charitable Trust
Contact: Thomas Burke, MD
Address: 22 Welgate Road, West Medford, MA 02155
Phone: 617-584-0064

2. Correspondent Information

Contact: Jonathan S. Kahan
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3. Date prepared:

October 25, 2019

4. Device Information

Device Name:	Ujenzi Charitable Trust's Every Second Matters – Uterine Tamponade Balloon
Common Name:	Intrauterine tamponade balloon
Regulation Number:	21 CFR 884.4530
Regulation Name:	Obstetric-gynecologic Specialized Manual Instrument
Regulatory Class:	Class II
Product Code:	OQY

5. Predicate Device Information

Device Name:	Bakri Postpartum Balloon, Bakri Postpartum Balloon with Rapid Instillation Component
510(k) Number:	K170622
Manufacturer:	Cook Incorporated
Regulatory Class:	Class II
Product Code:	OQY

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

6. Device Description

The Every Second Matters - Uterine Balloon Tamponade ("ESM-UBT") device is a single use product that consists of the kitting of 510(k)-cleared or off-the-shelf ("OTS") class I exempt components. The kit also contains an antiseptic prep pad that is marketed under an OTC monograph and is intended for use as an accessory with and during the assembly of the class I and class II medical device components of the ESM-UBT device:

- Urinary catheter
- Luer lock valve
- Condom
- Syringe

- Elastic O-ring
- Catheter holder
- Antiseptic (povidone iodine) prep pad

Ujenzi will ensure that the receiving specifications are correct for each component to be included in the ESM-UBT kit. The components will not be modified from their packaged state, and the entire kit will be re-labeled as the ESM-UBT device.

The ESM-UBT device can be placed following the failure of standard interventions for postpartum hemorrhage ("PPH"), which include active management of the third stage of labor ("AMTSL"): prophylactic use of a uterotonic medication (such as oxytocin), controlled cord traction for placental delivery, and uterine massage, and manual removal of the placenta and blood clot. The balloon presses on the vessels inside the uterus allowing the bleeding to be controlled.

Before placing the uterine balloon inside the uterus, the device will be assembled in an ISO certified clean room using the Foley urinary catheter, Luer lock valve, condom, and a green elastic O-ring. The condom needs to be rolled completely out and then secured to the end of the Foley catheter below the balloon side. The balloon on the Foley catheter should be inside the uterine balloon. The O-ring is used to attach the catheter to the balloon. The one-way Luer lock valve is located in the draining port of the urinary catheter and the syringe attaches to it.

The assembled condom-catheter is inserted into the bleeding uterus through the cervical opening. Prior to insertion, the surface of the assembled condom-catheter is wiped with an antiseptic prep pad. Upon placement within the uterine cavity, the balloon on the Foley catheter is inflated first with 15 mL of saline. This small balloon helps secure the catheter inside the uterus. One port on the Foley catheter is used for the syringe to inject saline into the small balloon, whereas the other port is used to inflate the condom balloon with saline. This condom balloon should be inflated until tamponade occurs as evidenced by bleeding cessation. The maximum fill volume of 500 mL was verified in bench tests. The device should be fixed to the thigh at the end using the catheter holder.

7. Indications for Use

The ESM-UBT device is intended to provide temporary control or reduction of postpartum uterine bleeding when conservative management is warranted.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The ESM-UBT and Bakri balloon (K170622) have identical intended use and indications for use, and similar technological characteristics and principles of operation. The Bakri balloon device consists of a double lumen silicone balloon catheter, a stopcock, and a 60 mL Luer-tip syringe. Similarly, the ESM-UBT also includes a silicone Foley catheter, Luer lock and a 60 mL syringe. Both uterine balloons of the devices can hold up to 500 mL of saline. One lumen of the Bakri catheter serves as the conduit through which saline is infused into the balloon after the catheter is inserted into the bleeding uterus. At the proximal end of the catheter in the Bakri device, a stopcock retains the saline in the balloon until a clinician gradually drains it allowing the uterus to contract. The Luer lock in the ESM-UBT device serves a similar function to this stopcock. Similar to the ESM-UBT device, the Bakri balloon provides compression against multiple sites of torn arteries, ruptured sinuses, lacerations and other sites of hemorrhage. The Bakri balloon also has a second lumen that provides a drainage port. The ESM-UBT device does not provide drainage. However, this difference does not affect the clinical use of the device as drainage ports are often obstructed with clotted blood and not used in actual practice.

The devices have differences with respect to sterility. Specifically, the entire Bakri Balloon is provided sterile, whereas the condom and O-ring components of the ESM-UBT are provided in their original, non-sterile packaging. Ujenzi will only use 510(k)-cleared condoms in the kit, which must adhere to ISO 4074 for natural rubber latex condoms among other standards, and an antiseptic pad is applied to the entire surface of the condom and O-ring before use. PVP-1 is a widely used antiseptic with broad microbicidal action spectrum efficiency. The microbial controls under ISO 4074 and PVP-1 application are sufficient for the condom and O-ring in the proposed intended use, and the benefit of responding to a life threatening postpartum hemorrhage greatly outweighs the low risk of contamination-related complications. Clinical data provided by Ujenzi was used to address these differences related to sterility and demonstrate substantial equivalence to the predicate device.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility studies, including Acute Systemic Toxicity, Intracutaneous Irritation Testing, Cytotoxicity and Sensitization testing were performed in accordance with the 2016 FDA guidance document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process"* and ISO 10993- 1:2009 as follows. In addition, Material Pyrogenicity testing and Hemolysis Assay was also conducted as noted below:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2006)
- Pyrogenicity testing (USP38-NF33:2015 <151>)
- Hemolysis assay (ASTM F 756)

The results of this testing demonstrated that the subject lubricant is biocompatible.

Mechanical Performance Testing

- Condom Diameter: Verification that the filled condom balloon has an appropriate diameter within the uterus.
- Burst Volume: Verification that the device has at least the burst volume of the predicate Bakri balloon.
- Device Integrity/Radial Pressure: Verification that the balloon can withstand a pressure higher than the normal intraluminal pressure of uterine balloon tamponade devices inside the uterus in a simulated system without leakage.
- Deflation Reliability: Verification that the device can be fully deflated and retrieved without rupture.
- Catheter Securement: Verification that the balloon on the Foley catheter can secure the device inside the uterus.
- O-ring Tensile Test: Verification that the O-ring maintains a connection between the condom balloon and catheter.

10. Clinical Data

Ujenzi provided peer-reviewed publications (listed below) to support use of the ESM-UBT device in the intended use population. Over 900 devices have been used in India, Tanzania, Kenya, Senegal, Sierra Leone, and Nepal. The results of the publications demonstrate the subject device is effective in managing PPH, led to high survival rates and low rates of complications. Ujenzi assessed the severity, expectedness,

and relatedness of each reported death and provided this information to an independent committee for review. All deaths observed to date have been expected due to the condition of the patients and unrelated to the ESM-UBT device. Interviews with healthcare workers also demonstrate that the device can be placed without difficulty, complication, or discomfort.

The sponsor provided the following publications:

- Burke TF, Ahn R., Nelson BD., et al. "A Postpartum Hemorrhage Package with Condom Uterine Balloon Tamponade: A Prospective Multi-Centre Case Series in Kenya, Sierra Leone, Senegal, and Nepal." Royal College of Obstetricians and Gynecologists 2015.
- Burke TF., Danso-Bamfo S., Guha M., Oguttu M., Tarimo V., Nelson BD. "Shock Progression and Survival After Use of a Condom Uterine Balloon Tamponade Package in Women with Uncontrolled Postpartum Hemorrhage." International Journal of Gynecology and Obstetrics 2017.
- Burke TF, Thapa K.,Shivkumar P., et al. "Time for Global Scale-Up, not Randomized Trials, of Uterine Balloon Tamponade for Postpartum Hemorrhage." Int J Gynecol Obstet 2018.
- Makin J., Suarez-Rebling DI, Shivkumar PV, et al. "Innovative Uses of Condom Uterine Balloon Tamponade for Postpartum Hemorrhage in India and Tanzania." Case Reports in Obstetrics and Gynecology 2018.
- Ramanathan A., Eckardt MJ., Nelson BD., Guha M., Oguttu M., Altawill Z., Burke TF. "Safety of a Condom Uterine Balloon Tamponade (ESM-UBT) Device for Use in Uncontrolled Postpartum Hemorrhage among Facilities in Kenya and Sierra Leone." BMC Pregnancy and Child Birth 2018.
- Tindell K., Garfinkle R., Abu-Haydar E., Ahn R., Burke TF, Conn K, Eckardt M. "Uterine Balloon Tamponade for the Treatment of Postpartum Haemorrhage in Resource-Poor Settings: A Systematic Review." BJOG 2012.
- A Low-Cost Uterine Balloon Tamponade Program for Uncontrolled PPH in India: A Two-Group Interrupted Time Series Evaluation" Harvard Medical School, Harvard T.H. Chan School of Public Health and Massachusetts General Hospital White Paper.
- Altawil Z., de Redon E., Dinh H., et al. "Uterine Balloon Tamponade for the Management of Uncontrolled Postpartum Hemorrhage by Midwives and Family Physicians." International Journal of Nursing and Midwifery 2017.
- Fehling M., Nelson, B.D., Ahn R., et al. "Development of a Community-Based Maternal, Newborn and Child Emergency Training Package in South Sudan." Public Health 2013.
- Natarajan A., Alaska AP., Nelson BD., Ahn R., Oguttu M., Dulo L., Eckardt MJ., Burke TF. "Provider Experiences with Improvised Uterine Balloon Tamponade for the Management of Postpartum Hemorrhage in Kenya." International Journal of Gynecology and Obstetrics 2016.
- Natarajan A., Chavez J., Ahn R., Nelson BD., Eckardt M., Dulo L., Achieng E., Oguttu M., Tester K., Burke TF. "Provider Experiences with Uterine Balloon Tamponade for Uncontrolled Postpartum Hemorrhage in Health Facilities in Kenya." International Journal of Gynecology and Obstetrics 2015.
- Natarajan A., Kamara J., Ahn R., Nelson BD., Eckardt MJ., Williams AM., Kargbo SA., Burke TF. "Provider Experience of Uterine Balloon Tamponade for the Management of Postpartum Hemorrhage in Sierra Leone." International Journal of Gynecology and Obstetrics 2016.
- Nelson BD, Ahn R, Fehling M., et al. "Evaluation of a Novel Training Package Among Frontline Maternal, Newborn, and Child Health Workers in South Sudan." International Journal of Gynecology and Obstetrics 2012.
- Nelson BD., Stoklosa H., Ahn R., Eckardt MJ., Walton EK., Burke TF. "Use of Uterine Balloon Tamponade for Control of Postpartum Hemorrhage by Community-Based Health Providers in South Sudan." International Journal of Gynecology and Obstetrics 2013.
- Pendleton AA., Natarajan A., Ahn R., Nelson BD., Eckardt MJ., Burke TF. "A Qualitative

Assessment of the Impact of a Uterine Balloon Tamponade Package on Decisions Regarding the Role of Emergency Hysterectomy in Women with Uncontrolled Postpartum Hemorrhage in Kenya and Senegal." BMJ Open 2016.

- Herrick T., Mvundura M., Burke TF., Abu-Haydar E. "A Low-Cost Uterine Balloon Tamponade for Management of Postpartum Hemorrhage: Modeling the Potential Impact on Maternal Mortality and Morbidity in Sub-Saharan Africa." BMC Pregnancy and Childbirth 2017.
- Mvundura M., Kokonya D., Abu-Haydar E., Okoth E., Herrick T., Mukabi J., Carlson L., Oguttu M., Burke T. "Cost-Effectiveness of Condom Uterine Balloon Tamponade to Control Severe Postpartum Hemorrhage in Kenya." International Journal of Gynecology and Obstetrics 2017.
- Nelson BD, Fehling M., Eckardt M., et al., "Innovative Package for Frontline Maternal, Newborn and Child Health Workers in South Sudan." South Sudan Medical Journal 2011.
- Pendleton AA, Natarajan A., Ahn R., et al. "Emergency Hysterectomy for Uncontrolled Postpartum Hemorrhage may be Averted Through Uterine Balloon Tamponade in Kenya and Senegal." International Federation of Gynecology and Obstetrics 2015.

11. Conclusion

The results of the performance testing and clinical data described above demonstrate that the Ujenzi Charitable Trust's Every Second Matters – Uterine Tamponade Balloon is as safe and effective as the predicate device and supports a determination of substantial equivalence.