November 13, 2023

SINAPI Biomedical (Pty) Ltd.
℅ Yolanda Smith
Regulatory Consultant
Smith Associates
1468 Harwell Ave
Crofton, Maryland 21114

Re: K230849
Trade/Device Name: ELLAVI UBT
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: OQY
Dated: March 27, 2023
Received: March 28, 2023

Dear Yolanda Smith:

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: 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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K230849

Device Name
ELLAVI UBT

Indications for Use *(Describe)*
The ELLAVI 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K230849

I. SUBMITTER

510(k) Owner
Chris de Villiers
SINAPI Biomedical (Pty) Ltd.
1 Lelie Street, ARC Infruitec, North Campus
Idas Valley, Stellenbosch, South Africa 7600
Phone: (+27) 021 887 5260
Email: sales@sinapibiomedical.com

Submission Correspondent
Yolanda R Smith, Regulatory Consultant
Smith Associates
Phone: (888) 729-9674
Email: ysmith@fdaconsultants.com

Date Prepared
November 9, 2023

II. DEVICE

Name of Device:	ELLAVI UBT
Common or Usual Name:	Intrauterine Tamponade Balloon
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 ELLAVI UBT is an 18 cm long intrauterine balloon tamponade device primarily comprised of thermoplastic elastomer. The balloon and internal tubing are made of thermoplastic elastomer, while the exterior tubing is made of polyvinyl chloride. A supply bag is the filled, connected, and hung at a pre-determined height based on the patient's systolic blood pressure. The device consists of a balloon that is inserted into the uterus transvaginally into the postpartum uterus after delivery and removal of the

placenta. A valve is then opened, and this allows the fluid to inflate the balloon and apply pressure to achieve a hemostatic effect.

V. INDICATIONS FOR USE

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

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

The table below compares the intended use and technological characteristics of the subject and predicate device.

Attribute	**K230849** **Subject Device:** **ELLAVI UBT**	**K170622** **Predicate Device:** **Bakri Postpartum Balloon** **Bakri Postpartum Balloon with Rapid Instillation Components**	**Comparison**
Manufacturer	SINAPI Biomedical (Pty) Ltd.	Cook Incorporated	N/A
Product Code	OQY	OQY	Same
Indications for Use	The ELLAVI UBT device 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 Components is intended to provide temporary control or reduction of postpartum uterine bleeding when conservative	Same

		management is warranted.	
Principle of Action	Inserted into the uterus and is inflated to press outward on the uterine walls, producing 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	Same
Design	Inflatable uterine balloon; no drainage side port	Inflatable uterine balloon and a single drainage side port	**Different**
Rx/OTC	Rx	Rx	Same
Materials	Thermoplastic elastomer	Silicone	**Different**
Sterile	SAL 10^{-6}	SAL 10^{-6}	Same
Single-use	Yes	Yes	Same
Balloon volume	400-750mL	500mL	**Different**
Balloon shape	Cylindrical	Round	**Different**
Catheter size	24F (8mm)	Not publicly available	**Different**
Number of catheter channels	1	2	**Different**
Uterine drainage	No	Yes	**Different**

The Indications for Use statement for the ELLAVI UBT is identical to the predicate device, except for the additional component included in the predicate 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:

- Design: The subject device expands to fill the entire uterine cavity and does not have a drain tube, whereas the predicate device has a single opening drain tube protruding out of the middle of the inflated balloon. The shape and size of the balloon are different.
- Materials: The patient contacting portions of the subject device is made of thermoplastic elastomer (balloon and internal tubing), while the predicate device is made of silicone.

These differences in technological characteristics do not raise different questions of safety and effectiveness. Non-clinical performance testing provided by SINAPI Biomedical (Pty) Ltd. was 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 at baseline and at the end of the three-year shelf-life:

- Visual Assessment – verification of no visual defects
- Dimensional Verification – verification of tube and balloon dimensions
- Stretch Percentage – Verify the stretch percentage of the balloon when filled with 750 ml
- Tube Kinking – Verify that the tube is unable to kink when handled as per normal use
- External Wall Pressure – The external wall of the balloon must be able to exert 60 mm Hg to 120 mm Hg on the uterine wall
- Pressure Maintenance – Verify that the balloon can maintain a pressure of 12 kPa for 20 seconds by p-test; Verify that the supply bag can maintain a pressure of 12 kPa for 8 seconds by p-test
- Balloon Burst Volume – Verify the burst volume of the balloon
- Balloon Leak/Rupture – Verify that the balloon and components show no sign of leakage and/or rupture when subjected to a hydrostatic pressure equal to 180 mm Hg for 24 hours
- Balloon Drop Strength – Verify that the balloon is able to withstand a drop from 1 m when filled to the maximum fill level
- Balloon Fill – Verify the time it takes to fill the balloon to the normal fill level for different supply bag heights
- Balloon Fill with Partial Blockage – Verify that the balloon is able to fill to the normal fill level while the inner tube is pressed against the balloon wall
- O-Ring Seal Force – Verify that the O-ring maintains a connection between the tube and the balloon
- Force to Separate the Balloon from the Tubing – Verify the force required to break the O-ring seal in case of emergency while the balloon is filled
- Balloon Leak in the Absence of an O-Ring – Verify if any leaks are present when the balloon is filled to its maximum operating fill level with no O-ring in place
- Tube/Tap Removal Force – Verify the force required to remove the tube from the tap
- Supply Bag/Tap Removal Force – Verify the force required as applied to the supply bag to pop the tube off the tap connection for a closed tap
- Balloon Draining Time – Verify the time it takes the balloon to drain back to the supply bag for different supply bag heights and tube orientations
- Balloon Fill with a Kinked Tube – Verify that the balloon can fill and/or drain with a kinked tube

Biocompatibility Testing

The ELLAVI UBT is a surface device in contact with a breached surface, with a limited contact duration (≤ 24 hours).

The biocompatibility evaluation for the ELLAVI UBT was conducted in accordance with the FDA September 2020 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 biocompatibility evaluation included the following tests:

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

The results demonstrate that the ELLAVI UBT is not cytotoxic, non-sensitizing, non-irritating, not acute systemically toxic, and does not elicit a material-mediated pyrogenic response.

Sterilization and Shelf-Life Testing

The ELLAVI UBT is sterilized using ethylene oxide to a SAL of 10^{-6}, according to ISO 11135:2014. A shelf-life of 3-years has been established based on accelerated aging in accordance with ASTM F1980-21. Simulated shipping distribution was conducted in accordance with ASTM D4196-16. Package integrity testing was conducted in accordance with ASTM F1980-16, F88/F88M-15, and ASTM F1929-15. Endotoxin testing was conducted in accordance with USP <85> to demonstrate less than <20 EU/device.

VIII. CONCLUSIONS

The non-clinical performance data described above demonstrate that the ELLAVI UBT is as safe and effective as the predicate device and supports a determination of substantial equivalence.