October 15, 2021

GTIMD LLC
Eran Levit
CEO
6 Columbia Drive
Amherst, NH 03031

Re: K202433
Trade/Device Name: Aqueduct 200 Cervical Dilation Balloon Catheter
Regulation Number: 21 CFR§ 884.4260
Regulation Name: Hygroscopic Laminaria Cervical Dilator
Regulatory Class: II
Product Code: PON
Dated: September 9, 2021
Received: September 13, 2021

Dear Eran Levit:

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,

For
Jason R. Roberts, 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)*
K202433

Device Name
Aqueduct 200 Cervical Dilation Balloon Catheter

Indications for Use *(Describe)*
The Aqueduct 200 Cervical Dilation Balloon Catheter is intended to be used whenever cervical softening and dilation is desired. Some examples are: treatment of cervical stenosis, IUD placement and removal, Radium placement, drainage of uterine cavity, endometrial biopsy, uterine curettage, suction cannula aspiration, operative hysteroscopy.

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 – K202433

I. Submitter

Submitter's Name:	GTIMD LLC
Address:	6 Columbia Drive, Amherst, NH 03031
Phone:	(603) 809-3089
Contact Person:	Eran Levit
Contact Email:	elevit@gtimd.com
Date of Preparation:	October 14, 2021

II. Device

Name of Device:	Aqueduct 200 Cervical Dilation Balloon Catheter
Common Name:	Catheter, Balloon, Dilation of the Cervical Canal
Regulation Number:	21 CFR 884.4260
Regulation Name:	Hygroscopic Laminaria Cervical Dilator
Regulatory Class:	II
Product Codes:	PON (Catheter, Balloon, Dilation of the Cervical Canal)

III. Predicate and Reference Devices

Predicate Device:
Aqueduct 100 Cervical Dilation Balloon Catheter (K160664) manufactured by GTIMD LLC

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

Reference Device:
Endosee Model 8000 U-scope (K123151) manufactured by Endosee Corp

IV. Device Description

The Aqueduct 200 Cervical Dilation Balloon Catheter is a balloon cervical dilation catheter which enables the simultaneous dilation of both sides of the cervical canal. The subject device is an updated version of the Aqueduct 100 Cervical Dilation Balloon Catheter cleared under K160664 that merges two separate dilation balloons into one balloon, removes the anchor balloon, replaces the four-way hub with a three-way hub, and removes the stylet from the shaft.

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The catheter consists of a 2-lumen shaft. One lumen inflates a cylindrical dilation balloon. A second lumen is for infusion of saline solution and also contains a camera and camera cable. In use, the catheter is inserted through the vagina and cervical canal and into the uterus. Using visual feedback from the forward-looking camera and LED light source the physician advances the catheter through the cervical canal and identifies the end of the canal when entering the internal orifice of the uterus. When the physician identifies the orifice, the catheter is positioned inside the cervix. This aligns the cylindrical dilation balloon at the internal cervical os and external cervical os. The balloon is inflated with 12.5 ml of saline, providing gradual mechanical dilation of the cervix.

The camera cable on the catheter connects to a camera module that provides power to the camera and allows connection to an HDMI port on a monitor to assess proper device placement during a clinical procedure. After 3 minutes of dilation of the internal and external orifices of the uterus, a controlled injection of 1-2.5 ml of saline may be made through the catheter infusion lumen which exits on the distal end of the catheter. Evidence that cervical dilation is complete can be determined once droplets of the saline injection are observed exiting through the external opening of the cervix. Optimal dilation of 8-9 mm within the cervical canal is typically achieved following 5 minutes of balloon dilation. The entire procedure from catheter insertion to removal is completed in 6-7 minutes.

The deflation of the balloon is conducted by attaching a luer lock syringe to the swabable valve and removing saline from the balloon.

The subject device is packaged in a mylar/Tyvek pouch and ethylene oxide (EO) sterilized to a SAL 10^{-6}. The packaged device has a shelf-life of 15 months.

V. Indications for Use

The Aqueduct 200 Cervical Dilation Balloon Catheter is intended to be used whenever cervical softening and dilation is desired. Some examples are: treatment of cervical stenosis, IUD placement and removal, Radium placement, drainage of uterine cavity, endometrial biopsy, uterine curettage, suction cannula aspiration, operative hysteroscopy.

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

The table below provides a comparison of the intended use and technological characteristics of the subject and predicate device:

	Subject Device **Aqueduct 200 Cervical Dilation Balloon Catheter (K202433)**	**Predicate Device** **Aqueduct 100 Cervical Dilation Balloon Catheter (K160664)**
Manufacturer	GTIMD LLC	GTIMD LLC
Regulatory Information	Hygroscopic Laminaria Cervical Dilator (21 CFR 884.4260) Product Code: PON Class II	Hygroscopic Laminaria Cervical Dilator (21 CFR 884.4260) Product Code: PON Class II
Indications for Use	The Aqueduct 200 Cervical Dilation Balloon Catheter is intended to be used whenever cervical softening and dilation is desired. Some examples are: treatment of cervical stenosis, IUD placement and removal, Radium placement, drainage of uterine cavity, endometrial biopsy, uterine curettage, suction cannula aspiration, operative hysteroscopy.	The Aqueduct 100 Cervical Dilation Balloon Catheter is intended to be used whenever cervical softening and dilation is desired. Some examples are: treatment of cervical stenosis, IUD placement and removal, Radium placement, drainage of uterine cavity, endometrial biopsy, uterine curettage, suction cannula aspiration, operative hysteroscopy.
Components	Balloon catheter with an incorporated camera and LED light source, and camera module	Balloon catheter
Balloon volume(s)	Dilation Balloon: 12.5 mL	Anchor Balloon: 2.5 mL Dilation Balloons: 7.5 mL (combined)
Balloon burst pressure	Dilation Balloon: > 8 atm	Anchor Balloon: > 2 atm Dilation Balloon: > 2 atm
Usable Length	25 cm	25 cm
Outer diameter	3.3 mm deflated and 12 mm	3.3 mm deflated and 12 mm

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	inflated	inflated
Shaft type	2-lumen polycarbonate shaft	3 lumen Pebax shaft
Materials	Pebax balloon, polyvinyl chloride hub, polycarbonate catheter, stainless steel	Pebax balloons and Pebax catheter
Dilation Mechanism	Fixed diameter balloon that expands to 12 mm	Fixed diameter balloons that expand to 12 mm
Stylet	No	Yes, unremovable
Shelf Life	15 months	2 years
Dilation Balloon Positioning Method	Optical using a CMOS camera and LED light	Mechanical using an anchor balloon
Saline flow?	Yes, single lumen for infusion	Yes, single lumen for infusion
Sterile/Reusable?	Single-use sterile device and reusable camera module	Single-use sterile device

The indications for use (IFU) for the subject device are identical to the predicate device IFU. Therefore, the intended use is the same – to dilate the cervix.

The subject device has different technological characteristics than the predicate device. The subject and predicate device have different device design specifications, number of balloons, materials, and positioning method.

The camera is used to position the dilation balloon, similar to the anchor balloon in the predicate device. Both features are used to aid in device placement.

These differences in technological characteristics do not raise different questions of safety and effectiveness as compared to predicate device (e.g., can the device be positioned correctly, are the materials biocompatible, can device use result in an injury to cervical or uterine tissues, etc.). Non-clinical performance data was conducted to address the technological differences between the subject and predicate device to demonstrate substantial equivalence.

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VII. Performance Data

To support the substantial equivalence of the subject device, the following performance testing was performed:

Biocompatibility Testing
Biocompatibility tests were conducted on the Aqueduct 200 Cervical Dilation Balloon Catheter according to the 2020 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"* as follows:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-10:2010)

The results of this testing demonstrated that the subject device is non-cytotoxic, non-irritating, and non-sensitizing.

Sterilization Validation
The subject device is ethylene oxide sterilized. The ethylene oxide sterilization cycle was validated using the overkill method, in accordance with ANSI/AAMI/ISO 11135:2014 *Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices*. Ethylene oxide residuals were evaluated according to ISO 10993-7:2008 *Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals*.

Packaging integrity and shipping testing were completed after accelerated aging to demonstrate the subject device packaging was able to withstand the rigors of shipping and distribution. Testing included seal strength (ASTM F88/F88M), dye penetration (ASTM F1929), shipping testing (ASTM D4169), and a visual inspection. The subject device met all the predetermined acceptance criteria.

Electrical Safety and Electromagnetic Compatibility (EMC)

The subject device was tested for electrical safety and EMC according to the following standards:

- IEC 60601-1:2005 (3rd Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

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- IEC 60601-1-2:2014, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
- 60601-2-18: Edition 3.0 2009-08, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

Optical Performance

The camera was evaluated for the following specifications and met the predetermined acceptance criteria:

- Component specifications
- Photobiological safety testing
- Field of view
- Direction of view
- Resolution
- Depth of field and optimum working distance
- Geometric distortion
- Noise and dynamic range
- Image intensity uniformity

Bench Performance Testing

Performance tests were performed on the Aqueduct 200 Cervical Dilation Balloon Catheter according to the requirements of ISO 10555-1:2013 and ISO 10555-4:2013 *Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements* and *Part 4: Balloon dilation catheters,* and ISO 11737-1:2018 *Sterilization of health care products —Microbiological methods Part 1: Determination of a population of microorganisms on products*.

Performance testing was also conducted on the Aqueduct 200 Cervical Dilation Balloon Catheter following an accelerated aging study to simulate a 15-month shelf life, including:

- Dimensional Verification
- Camera Functionality
- Balloon Burst Pressure
- Balloon Fatigue
- Balloon Inflation/Deflation Time
- Catheter Bond Strength
- Catheter Flexibility and Pushability

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- Balloon Preparation, Deployment, and Retraction

The subject device met the predetermined acceptance criteria for each test.

VIII. Conclusion

Based on the comparison and analysis above, the Aqueduct 200 Cervical Dilation Balloon Catheter is substantially equivalent to the predicate device.