November 6, 2020

GTIMD LLC
Eran Levit
Official Correspondent
6 Columbia Drive
Amherst, NH 03031

Re: K202427
Trade/Device Name: Aqueduct 100 Plus Cervical Dilation Balloon Catheter
Regulation Number: 21 CFR § 884.4260
Regulation Name: Hygroscopic Laminaria Cervical Dilator
Regulatory Class: II
Product Code: PON
Dated: September 30, 2020
Received: October 9, 2020

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
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202427

Device Name
Aqueduct 100 Plus Cervical Dilation Balloon Catheter

Indications for Use *(Describe)*
The Aqueduct 100 Plus 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 – K202427

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:	November 5, 2020

II. Device

Name of Device:	Aqueduct 100 Plus 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 Code:	PON (Catheter, Balloon, Dilation of the Cervical Canal)

III. Predicate Devices

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

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

IV. Device Description

The Aqueduct 100 Plus 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. In use, the catheter is inserted through the vagina and cervical canal and into the uterus. The catheter is positioned inside the cervix. The user aligns the cylindrical 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.

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 100 Plus 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 100 Plus Cervical Dilation Balloon Catheter (K202427)	Predicate Device Aqueduct 100 Cervical Dilation Balloon Catheter (K160664)
Manufacturer	GTIMD LLC	GTIMD LLC
Indications for Use	The Aqueduct 100 Plus 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.
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 10 mm inflated	3.3 mm deflated and 12 mm inflated
Shaft type	2-lumen polycarbonate shaft	3 lumen Pebax shaft
Materials	Pebax balloons and polycarbonate catheter	Pebax balloons and Pebax catheter
Dilation Mechanism	Fixed diameter balloons that expand to 10 mm	Fixed diameter balloons that expand to 12 mm
Stylet	No	Yes, unremovable
Shelf Life	15 months	2 years

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The Indications for Use statement for the subject device is the same as the predicate device. Therefore, the intended use of the subject and predicate devices are the same.

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

- The balloon volume and burst pressure specifications are increased for the subject device compared to the predicate device.
- The subject device balloon dimensions are different than the predicate device. The inflated diameter of the dilation balloon is less than the predicate device.
- The subject device includes one dilation balloon while the predicate device contains two separate dilation balloons and an anchor balloon.
- The number of lumens and component materials are different between the subject and predicate device.
- The subject device does not contain a stylet while the predicate device does.

These differences in technological characteristics do not raise different questions of safety and effectiveness as compared to the predicate device. Non-clinical performance data were used to address the differences related to design and materials to demonstrate substantial equivalence to the predicate device.

VII. Performance Data

To support the modifications to the subject device, the following design verification and validation activities were performed:

Biocompatibility Testing
Biocompatibility tests were conducted on the Aqueduct 100 Plus 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

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The subject device utilizes the same sterilization process as the predicate device and uses the same sterilization chamber and cycle. 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*.

Bench Performance Testing

Performance tests were performed on the Aqueduct 100 Plus 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 100 Plus Cervical Dilation Balloon Catheter following an accelerated aging study to simulate a 15 month shelf life, including:

- Dimensional Verification
- Balloon Burst Pressure
- Balloon Fatigue
- Balloon Inflation/Deflation Time
- Catheter Bond Strength
- Catheter Pushability

VIII. Conclusion

The Aqueduct 100 Plus Cervical Dilation Balloon Catheter has the same intended use as the predicate device. The subject device has different technological characteristics than the predicate device, but these differences do not raise different questions of safety and effectiveness. Finally, the submitted performance testing demonstrates that the subject device is as safe and effective as the predicate device. Therefore, the Aqueduct 100 Plus Cervical Dilation Balloon Catheter is substantially equivalent to the cleared predicate device.