DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 23, 2017

GTIMD LLC
Richard DeMello
Quality Manager
6 Columbia Drive
Amherst, NH 03031

Re: K160664
Trade/Device Name: Aqueduct 100 Cervical Dilation Balloon Catheter
Regulation Number: 21 CFR 884.4260
Regulation Name: Hygroscopic Laminaria Cervical Dilator
Regulatory Class: II
Product Code: PON
Dated: June 27, 2016
Received: July 1, 2016

Dear Richard DeMello,

This letter corrects our substantially equivalent letter of August 1, 2016.

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160664

Device Name
Aqueduct 100 Cervical Dilation Balloon Catheter

Indications for Use *(Describe)*
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.

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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GTIMD

510(K) SUMMARY

I. Submitter

Submitter's Name:	GTIMD LLC
Address:	6 Columbia Drive Amherst, NH 03031
Phone:	(603) 880-0277
Fax:	(603) 386-6422
Contact Person:	Richard DeMello
Date of Preparation:	January 23, 2017

II. Device

Name of Device:	Aqueduct 100 Cervical Dilation Balloon Catheter
Common Name:	Catheter, Balloon, Dilation of the Cervical Canal
Classification Name:	Hygroscopic Laminaria Cervical Dilator (21 CFR 884.4260)
Regulatory Class:	II
Product Code:	PON

III. Predicate Devices

Primary Predicate Device:
Dilapan-S (K143447) manufactured by Medicem Technology s.r.o.

Reference Device:
Cook Cervical Ripening Balloon (K131206) manufactured by Cook, Inc.

These predicate devices have not been subject to a design-related recall.

IV. Device Description

The Aqueduct 100 Cervical Dilator is a triple-balloon cervical dilation catheter which enables the simultaneous dilation of both sides of the cervical canal. The catheter consists of a 3-lumen shaft. One lumen inflates an anchoring balloon. A second lumen inflates the 2 cylindrical dilation balloons. The third lumen is for infusion of saline solution and also contains a fixed stiffening stylet to add rigidity to the catheter. The stylet is permanently sealed within the infusion lumen. In use, the catheter is inserted through the vagina and cervical canal and into the uterus where the distal spherical balloon is inflated. The catheter is then withdrawn until the spherical balloon comes into contact with the internal orifice of the uterus, which positions and anchors the catheter within the cervix. This aligns the two cylindrical balloons at the internal cervical os and external cervical os. The balloons are inflated with saline providing gradual mechanical dilation of the cervix.

After 3 minutes of dilation of the internal and external orifices of the uterus, a gentle, controlled injection of 1ml, and up to 2.5ml, of saline can be made through the catheter infusion lumen which exits between the two balloons (and inside the cervical canal). Evidence that cervical dilation is complete can be determined once droplets of the saline injection are observed entering through the external opening of the cervix. Optimal dilation of 8-9mm 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 Aqueduct 100 Cervical Dilator is packaged in a mylar/Tyvek pouch and EO sterilized to SAL 10^{-6}.

V. Indications For Use

The Aqueduct 100 Cervical Dilator 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.

VI. Comparison of Technological Characteristics

The design and function of the Aqueduct 100 Cervical Dilator is substantially equivalent to Dilapan-S (K143447) manufactured by Medicem Technology s.r.o. Both devices have the same intended use,

"whenever cervical softening and dilation is desired", and perform the comparable function "to dilate up to a 12mm diameter, in the case of Dilapan-S and 9mm diameter for the Aqueduct 100". The materials and mechanism of dilation are different as Dilapan-S is a hydrophilic polymer which relies on absorption of moisture to expand to its full diameter. The Aqueduct 100 is a polymer balloon that is inflated with a fixed volume of fluid to expand to its maximum diameter.
These differences do not raise different questions of safety and effectiveness

The Aqueduct 100 Cervical Dilatoris substantially equivalent in material, design and mechanism of operation to the Cook Cervical Ripening Balloon (K131206) manufactured by Cook, Inc.
Both devices have multi-lumen polymer shafts, two polymer dilation balloons located near the tip of the catheter, and a stiffening stylet. The Aqueduct 100 Cervical Dilator includes a third balloon for positioning and anchoring the catheter within the cervical canal. The dilation balloons on the Cook product are made from an elastomeric material which increases in size as more fluid is injected, so that they do not have a fixed length or diameter. The Aqueduct 100 Cervical Dilator has non-elastic, fixed dimension balloons that expand up to 12mm diameter. The catheter sizes are 18 French for the Cook catheter, while the Aqueduct 100 Cervical Dilator is 10 French. The useable length of the Cook catheter is 40cm. The Aqueduct 100 Cervical Dilator useable length is 25cm. Inflation volumes are 40ml to 80ml for the Cook device and 7.5ml for the Aqueduct 100.
These differences 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.

Biocompatibility Testing
Biocompatibility tests were conducted on the Aqueduct 100 Cervical Dilator according to the requirements of ISO 10993-1 Biological Evaluation of Medical Devices Part-1: Evaluation and Testing. The following tests were conducted:

- Cytotoxicity
- Sensitization
- Irritation

In Vitro Performance Testing

In vitro performance tests were performed on the Aqueduct 100 Cervical Dilator according to the requirements of ISO 10555-1, Sterile, Single Use Intravascular Catheters Part 1: General Requirements.
In-vitro performance testing conducted on the Aqueduct 100 Cervical Dilator included:

- Dimensional Verification
- Balloon Preparation, Deployment and Retraction
- Balloon Burst Pressure
- Balloon Fatigue
- Balloon Inflation/Deflation Time
- Catheter Bond Strength
- Resistance to Stylet Penetration

Conclusion

Based upon these biocompatibility and in vitro performance tests, the Aqueduct 100 Cervical Dilator has been shown to be substantially equivalent to the currently marketed Dilapan-S (K143447) manufactured by Medicem Technology s.r.o. and Cook Cervical Ripening Balloon (K131206) manufactured by Cook, Inc.