DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 17, 2015

Medicem Technology SRO
% Susanne Parks
US Regulatory Consultant
206 Ellington Road
Graham, NC 27253

Re: K143447
Trade/Device Name: Dilapan-S
Regulation Number: 21 CFR 884.4260
Regulation Name: Hygroscopic luminaria cervical dilator
Regulatory Class: II
Product Code: PKN
Dated: March 11, 2015
Received: March 17, 2015

Dear Susanne Parks,

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" (21 CFR 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 yours,

Benjamin R. Fisher -S

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)*
K143447

Device Name
Dilapan-S

Indications for Use *(Describe)*
Dilapan-S is to be used whenever cervical softening and dilation is desired. Some examples are:

1. Cervical stenosis
   a. related to dysmenorrhea
   b. considered a possible cause of infertility
   c. resulting from cauterization or conization
2. Placement and removal of intrauterine devices
3. Induction of labor
4. Radium placement
5. Drainage of uterine cavity
6. Endometrial biopsy
7. Uterine curettage
8. Suction cannula aspiration
9. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. 510(k) owner

Name	Medicem Technology s.r.o.
Address	Karlovarska Trida 20 Kamenne Zehrovice Czech Republic 27301
Telephone Number	00420775403437
fax	00420317070380
Contact Name	Adam Vlcek
Date 510(k) summary prepared	April 17, 2015

2. Device Information

Trade Name	DILAPAN-S
Common Name	Cervical Dilator
Classification Name	Hygroscopic Laminaria cervical dilator (21 CFR 884.4260)
Regulation Class	Class II
Product Code	PKN

3. Legally marketed device claiming substantial equivalence to

MedGyn Laminaria K880196

4. Description of Device:

DILAPAN-S is a hygroscopic cervical dilator that is manufactured from AQUACRYL, a proprietary hydrogel. The dilators are firm hygroscopic rods, similar in shape to natural laminaria tents. DILAPAN-S is capable of increasing in diameter on average from three (3) millimeters to 8.3-10

MEDICEM Technology s.r.o.
registered office at Kamenné Žehrovice, Karlovarská třída 20, Post Code 273 01, the Czech Republic
the company registered in the Commercial Register maintained by the Municipal Court in Prague on 26 November 1992,
Section C, Insert 15107, Company Id. No. 48036374
www.medicem.com

mm, or four (4) millimeters to 10-12.5 millimeters within 4-6 hours as they absorb moisture from the genital tract.

In clinical trials, DILAPAN-S has been shown to dilate the cervix gradually. It may not be necessary to use general or local anesthetics during the insertion process, thereby eliminating their associated risks to the patient. A Marker String is tied securely to the handle of the DILAPAN - S, and is provided to indicate location.

DILAPAN-S is capable of increasing its volume as it absorbs moisture from the genital tract through hygroscopic action. The volume of DILAPAN-S subsequently exerts radial pressure on the surrounding structures (uterine neck) to dilate progressively. Endocervical pressure on the uterine neck results in mechanical dilation and promotes cervical ripening through reversible cell dehydration and local endogenous prostaglandins release promoting collagen reorganization.

DILAPAN-S is available in boxes of 10 or 25 dilators and in the following dimensions: 4mm x 65mm, 4mm x 55mm, 3mm x 55mm. Each DILAPAN - S is individually wrapped in a single foil pouch and is sterilized by gamma radiation.

5. Intended Use

Dilapan-S is to be used whenever cervical softening and dilation is desired. Refer to section six for a comparison of the Indications for Use with the predicate.

6. Substantial Equivalence Discussion

6.1 Summary of Technological Charactersitics compared to the Predicate

DILAPAN-S has been designed as a synthetic bioanalogic dilator to improve upon the natural sea plant *Laminaria Japonica* contained in our predicate device. Below is a comparison:

Descriptor	Subject device (K143447)	Predicate device (K880196)
Device name	Dilapan-S	Laminaria
Regulation number	§884.4260	§884.4260
Product code	PKN	HDY
Indications	Dilapan-S is to be used whenever cervical softening and dilation is desired. Some examples are: 1. Cervical stenosis a. related to dysmenorrhea b. considered a possible cause of infertility c. resulting from cauterization or conization 2. Placement and removal of intrauterine devices	Laminaria should be considered wherever cervical dilation and/or softening of the cervix is desired. Some examples are: 1. Cervical stenosis a. Related to dysmenorrhea b. Considered a possible cause of infertility c. Resulting from cauterization or conization 2. Placement and removal of

<table>
<tr><td></td><td>3. Induction of labor
4. Radium placement
5. Drainage of uterine cavity
6. Endometrial biopsy
7. Uterine curettage
8. Suction cannula aspiration
9. Operative hysteroscopy</td><td>intrauterine devices
3. Induction of labor
4. Radium placement
5. Drainage of uterine cavity
6. Endometrial biopsy
7. Uterine curettage
8. Suction cannula aspiration</td></tr>
<tr><td>Mode of action</td><td>Same as the predicate device</td><td>1) By its absorption of fluid from the surrounding cervical tissue it expands in its diameter and dilates the cervical canal by exerting a radial pressure.
2) By pressure on cervical tissue it stimulates the endogenous prostaglandin production by initiating thearachidonic acid cascade causing collagen degradation which softens the cervix</td></tr>
<tr><td>Design</td><td>Rod of aquacryl is glued into a polypropylene handle. Signal String from surgical suture is attached to the handle.</td><td>Dried laminaria tent is drilled and attached to a 75-95 mm signal string</td></tr>
<tr><td>Size</td><td>3x55 mm
4x55 mm
4x65 mm</td><td>2 mm (Extra Small or Thin)
3 mm (Small or Thin)
4 mm (Medium)
5 mm (Large or Thick)
6 mm (Extra Large or Thick)
8 mm (Jumbo)
10 mm (Extra Jumbo)</td></tr>
<tr><td>Maximal time in situ</td><td>Same as the predicate device</td><td>24 hours</td></tr>
<tr><td>Key performance specifications</td><td><table><tr><td rowspan="2">Time in situ (hours)</td><td colspan="2">Expected dilation (in mm)</td></tr><tr><td>3 mm (dry)</td><td>4 mm (dry)</td></tr><tr><td>2</td><td>7.2-8.3</td><td>7.8-10.0</td></tr><tr><td>4</td><td>8.4-9.5</td><td>10.0-11.2</td></tr><tr><td>6</td><td>9.0-10.0</td><td>11.1-12.5</td></tr><tr><td>24</td><td>9.6-11.3</td><td>12.7-14.6</td></tr></table></td><td>Maximal dilation and softening occurs within about 12 hours</td></tr>
<tr><td>Material</td><td>Active part – Synthetic hydrogel (Aquacryl 90)
Signal string – Surgical suture
Handle – Polypropylene</td><td>Active part – Dried seaweed of Laminaria Japonica
Signal string – Unknown material</td></tr>
</table>

- The subject and predicate devices have the same general Indications for Use (IFU) and

examples of specific procedures, except that the subject device has an additional example – operative hysteroscopy. The difference does not raise any new types of questions because operative hysteroscopy is an established gynecological procedure. The difference raises a safety and effectiveness concern, but the clinical literature supports use of Dilapan-S for operative hysteroscopy.

- Technological characteristics – Mode of action
  Both subject and predicate devices are hygroscopic cervical dilators. They have the following same modes of action

  1) By absorption of fluid from the surrounding cervical tissue, they expand in diameter and dilate the cervical canal by exerting a radial pressure.
  2) By putting pressure on cervical tissue, they stimulate the endogenous prostaglandin production by initiating the thearachidonic acid cascade, causing collagen degradation, which softens the cervix.

- Technological characteristics – Design
  The subject device has three components (active part, handle, and signal string) whereas the predicate device has two components (active part and signal string). The difference raises a concern on the joint strength of the rod (active part)-handle and handle-signal string. However, joint strength is not a new type of question, because it is also associated with the predicate device and other hygroscopic cervical dilators. Also, there are well-established methods to evaluate joint strength. The company has provided sufficient mechanical engineering data to demonstrate that the subject device is safe and effectiveness.

- Technological characteristics – Size
  The subject device has three sizes with two diameters (3 mm and 4 mm), whereas the predicate device is available with seven (7) different diameters (2-10 mm). The difference does not raise any concerns because the subject device has a larger expansion force and can be used with multiple units at the same time. Clinical performance data show that the subject device, with narrowed dry diameter range, is as safe and effective as the laminaria devices.

- Technological characteristics – Key performance specifications
  Comparison of this parameter cannot be done, because we do not have data on the predicate device. However, clinical performance data show that the subject device is safe and effective.

- Technological characteristics – Material
  The subject device is made of synthetic hydrogel (Aquacryl 90) whereas the predicate device is manufactured with laminaria materials. The difference raises safety and effectiveness concerns; however, there are no new types of questions. The safety can be addressed by well-accepted biocompatibility testing, and the company has provided sufficient biocompatibility information. The effectiveness can be addressed by bench and clinical testing. The company has provided sufficiency mechanical performance data and clinical literature to establish the effectiveness of the subject device.

6.2 Summary of Non-Clinical and Clinical Performance Data to support determination of substantial equivalence

DILAPAN-S has been subjected to all biocompatibility tests as required by ISO 10993-1. Validation for sterilization including shelf life studies have been performed.

Comparison testing was performed with Laminaria. Swell testing,expansion force, comparisons of diameter variations and speed of swelling was assessed. Dilapan-S swells to greater diameters and faster rates than Laminaria, and also exerts greater forces during swelling.

The safe and effective use of DILAPAN-S has been previously shown in numerous clinical studies.

All data submitted demonstrate that DILAPAN-S is as safe and effective, and performs as well as or better than the predicate device.