August 23, 2019

CrossBay Medical
% Cindy Domecus, R.A.C.
Principal, Domecus Consulting Services
Domecus Consulting Services, LLC
1171 Barroihet Avenue
Hillsborough, CA 94010

Re: K190813
Trade/Device Name: CrossBay Cervical Dilator Catheter System
Regulation Number: 21 CFR 884.4260
Regulation Name: Hygroscopic Laminaria Cervical Dilator
Regulatory Class: Class II
Product Code: PON
Dated: July 22, 2019
Received: July 24, 2019

Dear Cindy Domecus:

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,

Sharon M. Andrews
Assistant Division 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)*
K190813

Device Name
CrossBay Cervical Dilator Catheter System

Indications for Use *(Describe)*
The CrossBay™ Cervical Dilator Catheter System is intended to be used whenever cervical softening and dilation is desired. Some examples are:

- Treatment of cervical stenosis
- IUD placement and removal
- Placement of instruments for intrauterine radiotherapy
- Endometrial biopsy
- Global endometrial ablation
- Uterine tissue removal
- Uterine curettage
- Diagnostic hysteroscopy
- Operative hysteroscopy

This device is not intended for use in the induction of labor.

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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K190813 510(k) Summary

I. SUBMITTER INFORMATION

Submitter: CrossBay Medical, Inc.
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San Diego, CA 92128

Submission Correspondent: Cindy Domecus, R.A.C. (US & EU)
Regulatory Consultant to CrossBay Medical
Phone: 650.343.4813
Fax: 650.343.7822
Email: domecusconsulting@comcast.net

Date Summary Prepared: August 23, 2019

II. SUBJECT DEVICE INFORMATION

Device Trade Name: CrossBay Cervical Dilator Catheter System
Common Name: Cervical balloon catheter
Regulation Number: 21 CFR §884.4260
Regulation Name: Hygroscopic Laminaria Cervical Dilator
Regulatory Class: II
Product Code: PON (catheter, balloon, dilation of cervical canal)

III. PREDICATE DEVICE INFORMATION

The predicate device is the Aqueduct 100 Cervical Dilation Balloon Catheter (K160664)

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

IV. DEVICE DESCRIPTION

The CrossBay Cervical Dilator Catheter System is a sterile, single use device composed of an inflation device, dilator catheter, everting membrane, and dilator balloon which enable softening and dilation of the cervical canal. The CrossBay Cervical Dilator Catheter System contains an Inflation Device and a Dilator Catheter that accesses the cervix using a hydraulic pressure-filled everting Membrane. The Inflation Device provides the hydraulic energy with saline supplied by the user. Once placed at the exocervix, the Dilator Catheter advances through the cervix by everting the Membrane through the

endocervix. A Dilator Balloon is attached to the inner tube of the device that is positioned across the cervix when the everting Membrane is fully everted. The Inflation Device is then used to further pressurize the system to split open the everting Membrane to expose the Dilating Balloon. The Inflation Device is used to pressurize the Dilator Balloon to the prescribed level. Once dilated, the Dilator Catheter is removed from the cervix and the subsequent uterine cavity procedure can commence.

The CrossBay Cervical Dilator Catheter with Dilator Balloon is provided in three sizes of 5mm, 7mm, and 9mm. The three sizes are identical except for the diameter of the Dilator Balloon when pressurized.

V. INDICATIONS FOR USE

The CrossBay™ Cervical Dilator Catheter System is intended to be used whenever cervical softening and dilation is desired. Some examples are:

- Treatment of cervical stenosis
- IUD placement and removal
- Placement of instruments for intrauterine radiotherapy
- Endometrial biopsy
- Global endometrial ablation
- Uterine tissue removal
- Uterine curettage
- Diagnostic hysteroscopy
- Operative hysteroscopy

This device is not intended for use in the induction of labor.

VI. SUBSTANTIAL EQUIVALENCE DISCUSSION

Comparison of Indications for Use

The table below presents a comparison of Indications for Use for the subject and predicate devices.

SUBJECT DEVICE **CrossBay Cervical Dilator Catheter System**	**PREDICATE DEVICE** **Aqueduct 100 Cervical Dilation Balloon Catheter, K160664**
The CrossBay™ Cervical Dilator Catheter System is intended to be used whenever cervical softening and dilation is desired. Some examples are: • Treatment of cervical stenosis • IUD placement and removal • Placement of instruments for intrauterine radiotherapy • Endometrial biopsy • Global endometrial ablation • Uterine tissue removal • Uterine curettage	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.

• Diagnostic hysteroscopy • Operative hysteroscopy This device is not intended for use in the induction of labor.	

The subject and predicate device have similar indications for use statements and have the same intended use – for softening and dilation of the cervix. The subject and predicate device list similar procedures for which the device can be used, with some differences in the examples provided for both the subject and predicate device. These procedures are performed following cervical softening and dilation. The listing of different procedures does not raise different questions of safety and effectiveness and does not change the intended use of the subject device.

Comparison of technological characteristics

The following technological similarities exist between the subject and predicate device:

- Both the subject and predicate device use a delivery catheter with a balloon for dilation of the cervix.
- Both the subject and predicate device employ saline as the pressurization media for the balloons.
- The subject and predicate device have similar working lengths and insertion depths

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

- The subject device utilizes an everting Membrane that advances with the Inner Catheter as the physician manually pushes the Inner Catheter into the Delivery Catheter to place the device across the cervix. Once positioned across the cervix, pressurized saline is used to split the everting Membrane to allow the Dilator Balloon to radially expand the cervix. The same manual advancement action is accomplished in the predicate device using a catheter to traverse the cervix. However, with the predicate device, once across the cervix, saline is pressurized within a separate distal balloon to position the device in the cervix. Within a second port, saline is injected into the dilation balloons to radially expand the cervix.
- The subject device has three (3) sizes of Dilator Balloons (5mm, 7mm, and 9mm) and the predicate device is labeled for a nominal diameter of 10mm.
- The subject device includes a 10 cc Inflation Device and the predicate device includes a 2.5 cc syringe within the package used to place saline within the catheter. For the predicate device, the 2.5 cc syringe is filled by the user three (3) times separately to pressurize the dilating balloons, whereas the Inflation Device of the subject device is anticipated to be filled once.
- The subject device is not deflated after dilation during removal from the cervix. The predicate device is deflated prior to removal from the cervix.
- The subject and predicate device use different materials in the construction of the catheter and balloon.

Different types of safety and effectiveness questions are not raised by the differences in technological characteristics.

VIII. PERFORMANCE DATA

The following non-clinical performance data were provided in support of the substantial equivalence determination:

Bench Testing

Physical bench testing confirmed that the CrossBay Cervical Dilator Catheter System performs according to the product specifications. Device evaluation consisted of the following physical and functional tests:

- Mechanical parameters
  - Visual inspection
  - Dimensional conformance
  - Initial inflation and cervical dilator preparation
  - Catheter pressurization
  - Membrane opening and evaluation
  - Dilation balloon performance
  - Inflation device performance
  - Bond/joint strength testing
  - Balloon volume maintenance
  - Balloon inflation/deflation time
  - Balloon fatigue
  - Balloon burst pressure
- Comparison testing of the subject device and predicate device to demonstrate functional equivalence
- Characterization of subject device performance using an anatomical model (extirpated uteri)

Biocompatibility

Biocompatibility testing was conducted according to ISO 10993-1 "Biological Evaluation of Medical Devices" and FDA's guidance "Use of International Standard ISO 10993-1" issued on June 16, 2016. Testing included the following:

- Cytotoxicity per ISO 10993-5:2009
- Vaginal Irritation per ISO 10993-10:2010
- Sensitization per ISO 10993-10:2010

Sterilization, Package Integrity, and Shelf life

The following assessments were performed to validate the sterilization, package integrity, and shelf life:

- Sterilization validation per ANSI/AAMI/ISO 11135:2014 and TIR28:2016
- Package integrity testing per ASTM F88/F88M-15 and ASTM F2096-11

- Simulated distribution and handling per ASTM D4169
- Accelerated shelf life testing of the mechanical parameters listed above per ASTM F1980-16

IX: CONCLUSIONS

The results of the performance testing described above demonstrate that the CrossBay Cervical Dilator Catheter System is as safe and effective as the predicate device and supports a determination of substantial equivalence.