CrossBay Medical Inc.
% Cindy Domecus, RAC (US & EU)
Principal, Domecus Consulting Services
Domecus Consulting Services, LLC
1171 Barroihet Drive
Hillsborough, CA 94010

Re: K192534
Trade/Device Name: CrossGlide™ ETS, Endometrial Tissue Sampler
Regulation Number: 21 CFR 884.1175
Regulation Name: Endometrial Suction Curette and Accessories
Regulatory Class: II
Product Code: HHK
Dated: February 20, 2020
Received: February 24, 2020

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,

For
Monica D. Garcia, Ph.D.
Acting 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)*
K192534

Device Name
CrossGlideTM ETS, Endometrial Tissue Sampler

Indications for Use *(Describe)*
The CrossGlideTM ETS, Endometrial Tissue Sampler, is indicated for use to remove material from the uterus and from the mucosal lining of the uterus by scraping and vacuum suction in order to obtain tissue for histological biopsy.

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- K192534

I. SUBMITTER INFORMATION

Submitter: CrossBay Medical Inc.
13240 Evening Creek Drive, Suite 304
San Diego, CA 92128

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

Date Summary Prepared: March 24, 2020

II. SUBJECT DEVICE INFORMATION

Device Trade Name: CrossGlide™ ETS, Endometrial Tissue Sampler
Common Name: Endometrial Sampling Device
Regulation Number: 21 CFR §884.1175
Regulation Name: Endometrial Suction Curette and Accessories
Regulatory Class: II
Product Code: HHK (Curette, Suction, Endometrial [and accessories])

III. PREDICATE DEVICE INFORMATION

The predicate device is the Marina Ampler Sampler (MAS), K021876.

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

IV. DEVICE DESCRIPTION

The CrossGlide™ ETS, Endometrial Tissue Sampler, is a sterile, disposable, single-use device which enables the removal of mucosal tissue from the uterus for histological biopsy. The CrossGlide™ ETS contains a Delivery Catheter with an everting Membrane and an Inner Aspiration Catheter. The everting Membrane places the Inner Aspiration Catheter into the uterine cavity. Movement of the ETS device, after creating negative pressure with the 3cc syringe, removes material and tissue from the uterine cavity.

V. INDICATIONS FOR USE

The CrossGlide™ ETS, Endometrial Tissue Sampler, is indicated for use to remove material from the uterus and from the mucosal lining of the uterus by scraping and vacuum suction in order to obtain tissue for histological biopsy.

VI. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Subject Device & Predicate Device	K192534	K021876	Comparison
Indications for Use	The CrossGlide™ ETS, Endometrial Tissue Sampler, is indicated for use to remove material from the uterus and from the mucosal lining of the uterus by scraping and vacuum suction in order to obtain tissue for histological biopsy.	The device is indicated for use to remove material from the uterus and from the mucosal lining of the uterus by scraping and vacuum suction in order to obtain tissue for histological biopsy or for menstrual extraction.	**Different:** The predicate device can also be used for menstrual extraction. However, both devices have the same intended use to remove endometrial tissue for biopsy samples
Device Components	Inner catheter, everting membrane, aspiration with hole, blue and white stopcock compliant tube, syringe	Catheter with syringe Catheter without syringe	**Different:** The subject device includes additional components as compared to the predicate device. These differences do not raise different questions of safety and effectiveness (S&E).
Aspiration Method	Manual	Manual	**Same**
Overall Catheter Length (cm)	43-48 cm	Unknown	**Different:** The length of the predicate device is not known. Differences in catheter length do not raise different questions of S&E.
Inner Catheter	Length: 315mm (includes Stopcock) Outer diameter: 2mm Internal diameter: 1.3mm	Not Applicable	**Different:** The predicate device does not include a separate inner catheter. Presence of an inner catheter and its length do not raise different questions of S&E.
Delivery Catheter	Length: 156mm (includes Acorn Tip)	Length Unknown 3-3.5 mm (OD)	**Different:** The length of the predicate device is not known;

	Outer diameter: 4.1mm Internal diameter 3.3.mm		however, its outer diameter is smaller than the subject device. The length and outer diameter of the subject device do not raise different questions of S&E.
Everting Membrane	Length: 65mm at full deployment Outer diameter: 3.5mm @ 3 atmospheres of pressure Wall thickness: 0.04mm	Not Applicable	**Different:** The predicate device does not include an everting membrane. Presence of an everting membrane in the subject device does not raise different questions of S&E.
Aspiration Device Side Hole & Internal Lumen	Side hole elliptical opening Internal lumen 1.3mm	Unknown	**Different:** The design of the tip opening and inner lumen of the predicate device is not known. Differences in tip design and internal lumen diameter do not raise different questions of S&E.
Acorn Tip	Length: 16mm Outer diameter: 12.4mm	Not Applicable	**Different:** The predicate device does not include an acorn tip. The presence of an acorn tip does not raise different questions of S&E.
Sterilization Method	Ethylene Oxide	Ethylene Oxide	**Same**

As noted in the table above, there are differences in the indications for use statements and technological features of the subject and predicate devices. However, as stated in the table, the differences in indications for use do not represent a new intended use, and the differences in technological features 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 testing was conducted according to ISO 10993-1 "Biological Evaluation of Medical Devices" and FDA's guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process." Testing included the following:

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

Sterilization Validation

The CrossGlide™ ETS was evaluated for adoption into the current ethylene oxide (EO) sterilization cycle of the contract sterilizer. The evaluation process was performed utilizing the AAMI Guidance contained in TIR28:2016 *Product adoption and process equivalence for ethylene oxide sterilization*. The EO Sterilization Cycle was validated in accordance with ANSI/AAMI/ISO 11135:2014. Residuals from the sterilization process were assessed and shown to be in accordance with ISO 10993-7:2008.

Packaging, Shipping Validation, and Shelf-Life

Packaging and shipping validation studies were conducted pursuant to the applicable ASTM guidelines (ASTM F88/F88M - 15 "Standard Test Method for Seal Strength of Flexible Barrier Materials"; and, ASTM F 2096-11 "Standard Test Methods for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble leaks)"; ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems). The shelf-life is supported by packaging and performance tests conducted on samples exposed to accelerated aging conditions pursuant to ASTM F1980 – 16 "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices". Additional assessments to support device function over its shelf-life included the following:

- Dimensional assessments
- Compliant tube ability to be distended and maintain targeted pressure
- Assessment of device eversion feature
- Evaluation of device marking to confirm correct deployment distance of the inner catheter beyond the everting membrane
- Negative pressure measurement to confirm ability to aspirate tissue samples
- Mechanical testing, including tensile joint strength, flexural testing and butt testing
- Leak testing
- Functional testing of the subject and predicate device to compare uterine deployment and specimen collection using a uterine model

VIII: CONCLUSIONS

The subject and predicate devices have the same intended use and comparable technological characteristics. The differences in technological characteristics between the

subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.