August 5, 2020

CrossBay Medical
% Cindy Domecus
Principal
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, CA 94010

Re: K201952
Trade/Device Name: CrossGlide™ ETS Plus
Regulation Number: 21 CFR 884.1175
Regulation Name: Endometrial Suction Curette and Accessories
Regulatory Class: II
Product Code: HHK
Dated: July 13, 2020
Received: July 14, 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,

Jason Roberts
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)*
K201952

Device Name
CrossGlide™ ETS Plus

Indications for Use *(Describe)*
The CrossGlide™ ETS Plus is indicated for use for sonohysterography and 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.

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510(k) Summary (21 CFR § 807.92(c))

I. SUBMITTER INFORMATION

Submitter: CrossBay Medical Inc.
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San Diego, CA 92128

Submission Correspondent: Cindy Domecus, R.A.C. (US & EU)
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Date Summary Prepared: August 3, 2020

II. SUBJECT DEVICE INFORMATION

Device Trade Name: CrossGlide™ ETS Plus
Common Name: Curette, Suction, Endometrial (And Accessories)
Regulation Number: 21 CFR §884.1175
Regulation Name: Endometrial suction curette and accessories
Regulatory Class: II
Product Code: HHK

III. PREDICATE DEVICE INFORMATION

The predicate device is the CrossBay™ Endometrial Tissue Sampler, K192534. The reference device is the CrossBay SonoSure™ Sonohysterography and Endometrial Sampling Device, K133144.

The predicate device and the reference device have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The CrossGlide™ ETS Plus is a sterile, disposable, single-use device which enables saline infusion sonohysteroraphy and the removal of mucosal tissue from the uterus for histological biopsy. The CrossGlide™ ETS Plus contains a Delivery Catheter with an everting Membrane, an Inner Aspiration Catheter that contains a lumen for saline infusion and aspiration. The everting Membrane places the Inner Aspiration Catheter into the uterine cavity. A proximal luer

connector allows a 10cc luer lock syringe to infuse saline into the uterine cavity for sonohysterography. The 10cc syringe can be used to remove the saline from the uterine cavity and create negative pressure. Movement of the CrossGlide™ ETS Plus device, after creating negative pressure with the 10cc syringe, removes material and tissue from the uterine cavity.

V. INDICATIONS FOR USE

The CrossGlide™ ETS Plus is indicated for use for sonohysterography and 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 INDICATIONS FOR USE WITH PREDICATE DEVICE

Table 1 below presents the Indications for Use for the subject and predicate devices, with the differences noted in bold font. The differences between the subject and predicate Indications for Use do not alter the intended use of the device. As a reference device is used in this submission, the Indications for Use for the reference device are also provided.

TABLE 1. COMPARISON OF INDICATIONS FOR USE

Subject Device **CrossGlide™ ETS Plus**	**Predicate Device, K192534** **CrossGlide™ ETS**	**Reference Device** **K133144** **CrossBay SonoSure™ Sonohysterography and Endometrial Sampling Device**
The CrossGlide™ ETS **Plus** is indicated for use for **sonohysterography and** 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 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 CrossBay SonoSure™ Sonohysterography and Endometrial Sampling Device is indicated for use to access the uterine cavity for saline infusion sonohysterography and to obtain endometrial biopsy, if indicated, utilizing the same device.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the subject and predicate device are compared below in **Table 2**.

	Subject Device **CrossGlide™ ETS Plus**	**Predicate Device** **K192534** **CrossGlide™ ETS**	**Reference Device** **K133144** **CrossBay SonoSure™ Sonohysterography and Endometrial Sampling Device**	**Comparison to Predicate Device**
Device Components	Inner catheter, everting membrane, aspiration with hole, blue and white pinch clamp, compliant tube, syringe	Inner catheter, everting membrane, aspiration with hole, blue and white stopcock, compliant tube, syringe	Delivery catheter, cytology brush, saline infusion bag, handle, acorn tip	**Different:** The subject device has the same components as compared to the predicate device except the blue and white stopcocks have been substituted by blue and white pinch clamps, which perform the same function. This difference does not raise different questions of safety and effectiveness (S&E).
Inflation Method	Manual, with 3cc syringe	Manual, with 3cc syringe	N/A	**Same**
Aspiration Method	Manual, with 10cc syringe	Manual, with 3cc syringe	N/A	**Same** aspiration method using different size of syringe
Overall Catheter Length (cm)	43-48 cm	43-48 cm	28 cm	**Same**
Inner Catheter	Length: 315mm (includes proximal connector and pinch clamp) Outer diameter: 2mm Internal	Length: 315mm (includes Stopcock) Outer diameter: 2mm Internal diameter: 1.3mm	N/A	**Same**

	Subject Device **CrossGlide™ ETS Plus**	**Predicate Device** **K192534** **CrossGlide™ ETS**	**Reference Device** **K133144** **CrossBay SonoSure™ Sonohysterography and Endometrial Sampling Device**	**Comparison to Predicate Device**
	diameter: 1.3mm			
Delivery Catheter	Length: 156mm (includes Acorn Tip) Outer diameter: 4.1mm Internal diameter 3.3.mm	Length: 156mm (includes Acorn Tip) Outer diameter: 4.1mm Internal diameter 3.3.mm	Length: 100mm (includes Acorn Tip)	**Same**
Everting Membrane	Length: 65mm at full deployment Outer diameter: 3.5mm @ 3 atmospheres of pressure Wall thickness: 0.04mm	Length: 65mm at full deployment Outer diameter: 3.5mm @ 3 atmospheres of pressure Wall thickness: 0.04mm	N/A	**Same**
Aspiration Device Side Hole & Internal Lumen	Side hole elliptical opening Internal lumen 1.3mm	Side hole elliptical opening Internal lumen 1.3mm	N/A	**Same**
Acorn Tip	Length: 16mm Outer diameter: 12.4mm	Length: 16mm Outer diameter: 12.4mm	Length: 22.5mm Outside diameter: 20.5mm	**Same**
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	**Same**
Saline Infusion Method	Manual (syringe)	NA	Same	**Different:** The predicate device is not indicated for saline infusion. As such, the reference

	Subject Device **CrossGlide™ ETS Plus**	**Predicate Device** **K192534** **CrossGlide™ ETS**	**Reference Device** **K133144** **CrossBay SonoSure™ Sonohysterography and Endometrial Sampling Device**	**Comparison to Predicate Device**
				device is included to provide scientific and technical information to address the safety and effectiveness of the saline infusion capability of the subject device.

At a high level, the subject and predicate devices comprise the following same technological elements:

- Both the subject and predicate device use a delivery catheter to place the aspiration device into the uterine cavity to remove material.
- Both the subject and predicate device employ a syringe to apply vacuum on the aspiration device.
- Both the subject and predicate device use similar materials in the construction of the catheter.
- Both the subject device and predicate device utilize everting Membrane technology using the same materials, configuration, dimensions, and hydraulic principle for crossing the cervical canal.
- Both the subject device and the predicate device have the same sterilization method, packaging construction and materials.

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

- The subject device uses a 10cc syringe to apply vacuum suction to the Aspiration Device. The predicate device uses a 3cc syringe to apply vacuum suction.
- The subject device utilizes a Blue Pinch Clamp and a White Pinch Clamp as one-way valves (on/off). The predicate device utilizes a Blue Stopcock and White Stopcock as one-way valves in the same locations on the catheter. The stopcock and pinch clamp share the same function and performance characteristics.
- The subject device utilizes a 10cc syringe to infuse saline trough the catheter and into the uterine cavity.

The differences in technology do not raise different questions of safety and effectiveness, as both the subject and predicate device operate to transfer fluid/tissue through the catheter via manual pressure.

VIII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Bench Testing

Physical bench testing confirmed that the CrossGlide™ ETS Plus performs according to the product specifications. Device evaluation consisted of physical and functional testing performed pursuant to test protocols that were used to support clearance of the predicate or reference device. Mechanical testing, including tensile and pressurization testing, was conducted to determine if the pinch clamps could operate during expected functional conditions. Additional pressurization testing was conducted to determine if the use of a 10cc syringe can maintain adequate negative pressure required for sample collection. The subject device successfully passed all functional bench testing (i.e., met predefined acceptance criteria).

Biocompatibility testing

The subject device utilizes identical materials and manufacturing as the predicate device. Therefore, biocompatibility testing on the predicate device, which was conducted according to ISO 10993-1 "Biological Evaluation of Medical Devices" and FDA's guidance "Use of International Standard ISO 10993-1", final document issued on June 16, 2016 can be leveraged to support the biocompatibility of the subject device. Testing included the following with passing results: 1) Cytotoxicity, 2) Vaginal Irritation, and 3) Sensitization.

Sterilization Validation

The subject device utilizes the same product design and packaging as the predicate device. The predicate device 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 originally validated in 2016, using the overkill method, in accordance with ANSI/AAMI/ISO 11135:2014. The results and conclusion of this evaluation confirmed that the subject device could be adopted into the previously validated cycle.

Packaging, Shipping Validation, and Shelf-Life

The subject device utilizes the same product design and packaging as the predicate device. 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, using Distribution Cycle 13. 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".

IX: CONCLUSIONS

The CrossGlide™ ETS Plus Sonohysterography and Endometrial Tissue Sampler has the same intended use as the predicate device. There are differences in the indications for use statements for the subject and predicate devices. The differences between the subject and predicate Indications for Use do not alter the intended use of the device. In addition, the subject device has the similar technological characteristics as the predicate device and the differences do not raise different questions of safety and effectiveness. Finally, the submitted testing demonstrates that the subject device is as safe, as effective, and performs as well as the predicate device. Therefore, the CrossGlide™ ETS Plus is substantially equivalent to the cleared predicate device.