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

January 5, 2017

CrossBay Medical Inc.
% Cindy Domecus
Principal
Domecus Consulting Services, LLC
1171 Barroihet Drive
Hillsborough, CA 94010

Re: K162064
Trade/Device Name: CrossBay IVF Embryo Transfer Catheter Set
Regulation Number: 21 CFR 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: Class II
Product Code: MQF
Dated: December 5, 2016
Received: December 7, 2016

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. 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,

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)*
K162064

Device Name
CrossBay IVF Embryo Transfer Catheter Set

Indications for Use *(Describe)*
The CrossBay IVF Embryo Transfer Catheter Set is intended for ultrasound-guided introduction of embryos into the uterine cavity following in vitro fertilization.

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)) K162064

I. SUBMITTER INFORMATION

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Date Summary Prepared: January 4, 2017

II. SUBJECT DEVICE INFORMATION

Device Trade Name:	CrossBay IVF Embryo Transfer Catheter Set
Common Name:	Embryo Transfer Catheter
Classification Name:	Assisted Reproduction Catheters (21 CFR §884.6110)
Regulatory Class:	II
Submission Type:	Traditional 510(k)
Product Code:	MQF – Catheter, Assisted Reproduction

III. PREDICATE DEVICE INFORMATION

- Wallace Sure View™ Embryo Replacement Catheters & Trial Transfer Catheters (K033084)

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

IV. DEVICE DESCRIPTION

The CrossBay IVF Embryo Transfer Catheter Set is a sterile, single use device composed of disposable components supporting the transfer of an *in vitro* fertilized embryo to the uterus.

The CrossBay IVF Embryo Transfer Catheter Set is comprised of a Delivery Catheter with a 6 Fr Inner Catheter and everting membrane that accesses the cervix and uterine cavity; a 3cc syringe for supplying aseptically filtered media or saline to the Delivery Catheter; and a 3 Fr Embryo Transfer Catheter that is supplied in a separately sealed pouch. The Delivery Catheter contains an acorn tip for seating the distal end of the Delivery Catheter at the exocervix. The Embryo Transfer Catheter contains a stainless steel band at the distal end to provide additional echogenicity to the catheter for ultrasound guided

procedures. The Embryo Transfer Catheter has markings on its proximal end at 1 cm intervals to aid in determining the depth of insertion. The Embryo Transfer Catheter can extend a maximum distance of 4 cm beyond the distal end of the fully everted membrane when completely inserted into the Delivery Catheter. The maximum insertion depth of the Embryo Transfer Catheter and fully everted membrane is 9 cm.

The 3 cc syringe is used for priming the device and supplying aseptically filtered culture media or sterile saline to pressurize the Delivery Catheter for the purposes of membrane deployment. Aseptically filtered culture media or saline is introduced into the Delivery Catheter until hand resistance on the 3 cc syringe is felt. Once loaded with aseptically filtered culture media or saline, the Inner Catheter is manually advanced to introduce the everting membrane and Inner Catheter into the endocervix and uterine cavity. When fully everted, the Inner Catheter advances 5 cm across the cervical canal into the uterine cavity. The 3 Fr Embryo Transfer Catheter loaded with embryo(s) is inserted through the Inner Catheter and into the uterus.

V. INDICATIONS FOR USE

The CrossBay IVF Embryo Transfer Catheter Set is intended for ultrasound-guided introduction of embryos into the uterine cavity following in vitro fertilization.

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

Comparison of Intended Use

The indications for use for the subject and predicate device are shown in Table 1 below:

Table 1: Indications for Use for the Subject and Predicate Device

CrossBay IVF Embryo Transfer Catheter Set (K162064)	Wallace Sure View™ Embryo Replacement Catheters & Trial Transfer Catheters (K033084)
The CrossBay IVF Embryo Transfer Catheter Set is intended for ultrasound-guided introduction of embryos into the uterine cavity following in vitro fertilization.	Embryo Replacement Catheters are sterile, single-use devices for ultrasound guided introduction of embryos into the uterine cavity following in-vitro fertilization. Trial Transfer Catheter are sterile, single-use devices for determining whether the cervix is passable for a Wallace embryo replacement catheter.

As shown in the table above, the indications for use of the CrossBay IVF Embryo Transfer Catheter Set are not the same as the predicate Wallace Sure View™ Embryo Replacement Catheters & Trial Transfer Catheters (K033084). The subject and primary predicate devices do have comparable indication statements in regards to transferring embryos into the uterus under ultrasound guidance. However, the primary predicate device also included trial transfer catheters indicated for use in determining whether the cervix is passable before attempting an embryo transfer procedure. As trial transfer catheters are not required to complete an embryo transfer procedure, this difference does not represent a new intended use for the subject device (i.e., transferring embryos into the uterus under ultrasound guidance).Therefore, the subject and predicate devices have the same intended use.

Technological Characteristics

A detailed comparison of the technological characteristics of the subject and predicate device is provided in Table 2 below:

Table 2: Technology Comparison of the Subject Device and Predicate Device

Design Characteristics	CrossBay IVF Embryo Transfer Catheter Set (K162064)	Wallace Sure View™ Embryo Replacement Catheters & Trial Transfer Catheters (K033084)	Comparison
System Components	Delivery catheter (incorporating the inner catheter and everting membrane), embryo transfer (ET)catheter, and 3 cc syringe	Outer delivery catheter, ET catheter, trial transfer catheter.	Different: The subject device incorporates an everting membrane that is deployed as the inner catheter is advanced through the cervical canal. The inclusion of these components provides a padded (fluid-filled) layer around the inner catheter as it passes through the cervix. The inclusion of these components does not raise different questions of safety and effectiveness (S & E) as compared to the predicate (e.g., ability to advance through cervix, ability to support passage

			of ET catheter, perforation, etc.). The subject device also includes a 3 cc syringe for device preparation and deployment. This component is supplied as a convenience to the user and does not raise different questions of S & E. The predicate includes an optional trial transfer catheter that may be used to assess whether the cervix is passable before delivering the ET catheter. Lack of a trial transfer catheter does raise different questions of S & E.
Device Materials of Embryo Transfer Catheter	Pellethane polyurethane tubing, polypropylene hub	Information is unknown	Different: The materials in the predicate device are not known; however, differences in device materials do not raise different S & E questions (e.g., biocompatibility, embryo compatibility)
Device Materials of Delivery Catheter	Pebax, polyurethane, low density polyethylene, ABS	Information is unknown	Different: The materials in the predicate devices are not known; however, these differences do not raise different S & E questions (e.g., biocompatibility)
Device Markings	Three (3) marks of 1 cm increments on proximal end of Embryo Transfer Catheter	Four (4) marks of 1 cm increments on proximal end of embryo transfer catheter and five (5) marks on the distal end of the outer delivery catheter.	Different: The ET catheters both include 1 cm increment depth marks to aid in assessing insertion depth. However, the subject delivery catheter does not include depth marks like the predicate. The subject device

			incorporates an acorn tip on the delivery catheter that is positioned at the exocervix to control the depth of insertion of the delivery catheter. Lack of depth marks on the subject device delivery catheter does not raise different S & E questions.
Depth of insertion into the uterine cavity	The Delivery Catheter is used to traverse the cervix for a distance of 5 cm from the acorn tip at the exocervix with a fully everted membrane. The embryo transfer catheter is inserted through the fully everted Delivery Catheter. Four markings in 1 cm increments on the proximal end of the Embryo Transfer Catheter indicates insertion beyond the distal end of the everted membrane.	The outer delivery catheter is used to traverse the cervix. Outer delivery catheter has five (5) 1 cm increments indicating depth of insertion in the cervix. The embryo transfer catheter is inserted into the outer delivery catheter. The embryo transfer catheter protrudes from the outer delivery catheter by 4 cm. Four markings in 1 cm increments on the proximal end of embryo transfer catheter indicates insertion beyond the distal end of the outer delivery catheter.	Similar
Physical dimensions of device components (length, ID, OD) of the Embryo Transfer Catheter	Length: 31 cm ID: 0.56 mm OD: 0.91mm	Length: 18 to 23 cm ID: 0.76 mm OD: 1.5 mm	Different: The overall length of the subject ET catheter is longer than the predicate; however, the overall maximum depth of insertion into the uterine cavity is similar due to inclusion of the acorn tip on the delivery catheter that limits ET catheter insertion depth into the uterine

			cavity. In addition, the ID and OD of the subject device are smaller than the predicate. These differences do not raise different S & E questions.
Physical dimensions of device components (length, ID, OD) and overall device length of the Delivery Catheter	Overall Length: 23 cm fully everted ID: 1.17mm OD: 1.55 mm (OD of the inner catheter at the distal end of the delivery catheter	Overall Length of Delivery Catheter: Unknown Inner diameter unknown, 2.3 mm OD of outer delivery catheter	Different: The specific length of the predicate delivery catheters is unknown, but based on device design is anticipated to be shorter than the ET catheter (~4 cm shorter). Therefore, the subject delivery catheter is longer than the predicate devices. The subject device incorporates an acorn tip on the delivery catheter that is positioned at the exocervix to control the depth of insertion of the delivery catheter. In addition, the subject device has a smaller OD than the predicate device. These differences do not raise different S & E questions.
Embryo Transfer Catheter tip configuration	Rounded tip with opening at distal end	Rounded tip with opening at distal end	Same
Ultrasound guidance marker	Stainless steel marker band at distal end of Embryo Transfer Catheter	Air bubbles enclosed within polyurethane material	Different: Different types of echogenic markers used in the subject and predicate devices. Differences in ultrasound visualization methods do not raise different S & E questions.
Procedural steps: Placement into uterine cavity	1. Pressurize Delivery Catheter 2. Fully evert Delivery	1. Insert outer delivery catheter across cervix 2. Insert loaded embryo	Similar

	Catheter across cervix 3. Insert loaded Embryo Transfer Catheter through Delivery Catheter 4. Deposit embryo(s)	transfer catheter through outer delivery catheter 3. Deposit embryo(s)	
Sterilization method and use	Ethylene Oxide (EtO) sterilized and single use	EtO sterilized and single use	Same
MEA specification	One cell mouse embryo tested (MEA) showing a ≥ 80% blastocyst formation rate at 96 hours.	Two cell mouse embryo tested (MEA) showing a > 80% survival.	Different: Different versions of MEA testing used. These differences do not raise different S &E questions.
Endotoxin specification	Endotoxin (LAL): ≤20 EU/device Testing is conducted on a lot-to-lot (batch) basis	Endotoxin (LAL): 0.5 EU/ml Testing is conducted on a lot-to-lot (batch) basis	Different: The acceptance specifications used are different, but do not raise different S & E questions.

As noted in the table above, the subject and predicate device are similar in that they are both EtO-sterilized, single-use, polymer-based catheters consisting of an outer delivery system used to traverse the vaginal cavity and cervix, and a transfer catheter used to hold and deliver embryos into the uterine cavity. Both the subject and predicate devices include depth markers on the embryo transfer catheter to assess insertion depth into the uterine cavity. However, differences do exist as described in the table above (e.g., inclusion of an everting membrane, dimensions, specific device materials, etc.). The differences identified do not raise different questions of safety and effectiveness as discussed in Table 2.

VII. PERFORMANCE DATA

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

Bench Testing

Physical bench testing confirmed that the CrossBay IVF Device performs according to the product specifications. Device evaluation consisted of dimensional testing, visual inspection, physical and functional testing including: eversion and inversion of the Delivery Catheter, passage of the Embryo Transfer Catheter through the Delivery Catheter, bond joint testing, and over-pressurization testing. Performance testing also included tensile testing on all bond joints to demonstrate component integrity beyond anticipated operational forces. Membrane integrity and burst testing demonstrated their ability to withstand pressurization forces beyond those expected in use. Verification testing was conducted to demonstrate that the catheter prepping procedure provides the expected catheter performance.

Additional comparative testing performed with the subject device and predicate device supported equivalence by demonstrating functional equivalence of the subject device and predicate devices. Demonstrations of functional equivalence included navigating tubing with varying lumen diameters and bend radii with both the subject and predicate devices. The Embryo Transfer Catheters were also comparison tested for cantilevering in free space, ability to withstand radius of curvature without deformation, degree of compressive force recorded when the distal end of the embryo transfer catheters is pressed into a force gauge, and the ability of the subject and predicate embryo transfer catheters to pick up and inject discrete micro-liters of fluid.

Biocompatibility testing

Biocompatibility testing was conducted on sterile CrossBay Medical IVF devices. Biocompatibility testing was conducted according to ISO 10993-1- 2009/(R2013) "Biological Evaluation of Medical Devices" and FDA's recent guidance "Use of International Standard ISO 10993." Testing included the following: 1) Cytotoxicity (ISO 10993-5:2009); 2) Vaginal Irritation (ISO 10993-10:2010); and, 3) Sensitization (ISO 10993-10:2010). The test articles assessed provided acceptable results as no signs of cytotoxicity, sensitization or irritation reactions were noted in testing.

Endotoxin Testing

Bacterial Endotoxin (Limulus Amoebocyte Lysate) Assay testing (FDA recognized consensus standard USP<85> and ANSI/AAMI ST72:2011) was performed on three lots of product demonstrating that devices met the acceptance specification of ≤20 EU/device. Endotoxin testing is performed on each lot of product.

Mouse Embryo Assay (MEA) Testing

Mouse Embryo Assay Testing was performed on the Embryo Transfer Catheter both before and after 6 months of accelerated aging on three lots of product with one cell mouse embryo testing (MEA) demonstrating that devices met the acceptance specification of ≥80% blastocyst formation at 96 hours. Test articles passed all MEA testing conducted. MEA testing is performed on each lot of product.

Sterilization Validation

The sterilization validation was performed in compliance with the requirements in the applicable standards for ethylene oxide sterilization (ISO 11135-1:2014 "Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices" and ISO 10993-7:2008 "Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals").

Packaging, Shipping Validation, and Shelf-Life

Packaging and shipping validation studies were conducted on sterilized CrossBay IVF Devices 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)"; ISTA 2A:2011 "Preshipment Testing procedures – Combination tests for Packaged Products Weighing 150lbs (68kg) or less"). The proposed shelf-life of six (6) months is supported by packaging and performance tests conducted on samples exposed to accelerated aging conditions pursuant to ASTM F1980 – 07 "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices". The parameters assessed before and after aging included functional, dimensional testing, visual inspection, bond and joint testing, over-pressurization testing, and MEA testing.

VIII: CONCLUSIONS

The subject and predicate devices have the same intended use and technological characteristics. Based on the intended use, technological characteristics, and bench performance data provided in this premarket notification, the CrossBay IVF Embryo Transfer Catheter Set has been shown to be substantially equivalent to the predicate device.