May 1, 2020

Kitazato Corporation
% Audrey Swearingen
Regulatory Affairs Manager/Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, TX 78746

Re: K192540
Trade/Device Name: Kitazato ET Catheters (Type 1 [Versions 1-4], Type 2 [Versions 1-5], and Type 3 [Versions 1-4])
Regulation Number: 21 CFR§ 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: II
Product Code: MQF
Dated: April 1, 2020
Received: April 2, 2020

Dear Audrey Swearingen:

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)*
K192540

Device Name

Kitazato ET Catheters (Type 1 [Versions 1-4], Type 2 [Versions 1-5], and Type 3 [Versions 1-4])

Indications for Use *(Describe)*

Kitazato ET Catheters are 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

Kitazato ET Catheter

1. Submission Sponsor

Kitazato Corporation
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Tokyo 105-0012
Japan
Contact: Mr. Futoshi Inoue
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Title: President and Representative Director

2. Submission Correspondent

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Austin, TX 78746
Office Phone: (512) 327-9997
Contact: Audrey Swearingen
Title: Regulatory Affairs Manager/Senior Consultant

3. Date Prepared

April 28, 2020

4. Device Identification

Trade/Proprietary Name:	Kitazato ET Catheters (Type 1 [Versions 1-4], Type 2 [Versions 1-5], and Type 3 [Versions 1-4])
Common/Usual Name:	Embryo Transfer Catheter
Regulation Name:	Assisted Reproduction Catheters
Regulation Number:	884.6110
Product Code:	MQF (Catheter, Assisted Reproduction)
Class:	Class II

5. Legally Marketed Predicate Device(s)

Guardia™ Access Embryo Transfer Catheter Sets (Cook Incorporated), K173686.

This predicate device has not been subject to any design related recalls.

6. Indication for Use Statement

Kitazato ET Catheters are intended for ultrasound guided introduction of embryos into the uterine cavity following in vitro fertilization.

7. Device Description

Kitazato ET Catheters are sterile, single-use catheters for use in embryo transfer procedures.

The catheter is used to hold and deliver embryos to the uterine cavity during a procedure. Catheters are available in 3Fr and 4Fr sizes, both of which are provided in lengths of 220 mm and 250 mm, as well as one version that is 3Fr and 400 mm length that has the same uterine insertion depth as the other device versions, but allows the user to be positioned further from the patient during a procedure. Devices also include versions with and without an echo reflective chip in the tip of the catheter. The echo reflective chip aids in visualization of the catheter during a transfer procedure; however, all transfer procedures are to be done under ultrasound guidance. Both the Type 1 and Type 2 devices also include a stainless steel or polyimide core to provide additional rigidity to the catheter.

The guide is used to navigate the pathway through the cervical canal to allow for easier catheter insertion Guides are provided with a 30° pre-curved distal shaft and are available in lengths of 170 mm and 200 mm. Guides also include a styrene elastomer stopper to aid in positioning the guide to the targeted uterine insertion depth. The guides are also available with a straight or bulb tip design, and with and without an echo reflective chip in the tip of the guide. An obturator with a length of 170 mm or 200 mm is provided with the Type 2 versions of the device to prevent ingress of fluid into the guide lumen during guide insertion.

The Stylet is an optional accessory used when additional rigidity is needed during insertion of the guide through the cervix, and is provided in two lengths, 170 mm and 200 mm. The stainless steel core of the Stylet can be shaped to aid in guide delivery through the cervix.

A summary of the different device versions included in this submission are shown in the tables below:

Type	**Size**	**Version Components**		
		Catheter	**Guide**	**Obturator**
Type1-v1	3Fr	220 mm ET Catheter	170 mm Guide (curved) bulb tip	-
Type1-v2	3Fr	250 mm ET Catheter	200 mm Guide (curved) bulb tip	-
Type1-v3	4Fr	220 mm ET Catheter	170 mm Guide (curved) straight tip	-
Type1-v4	4Fr	250 mm ET Catheter	200 mm Guide (curved) straight tip	-

Type2-v1	3Fr	220 mm ET Catheter	170 mm Guide (curved) bulb tip	170 mm Obturator
Type2-v2	3Fr	250 mm ET Catheter	200 mm Guide (curved) bulb tip	200 mm Obturator
Type2-v3	4Fr	220 mm ET Catheter	170 mm Guide (curved) straight tip	170 mm Obturator
Type2-v4	4Fr	250 mm ET Catheter	200 mm Guide (curved) straight tip	200 mm Obturator
Type2-v5	3Fr	400 mm ET Catheter	200 mm Guide (curved) bulb tip	200 mm Obturator

Type	**Description**
Type3-v1	3Fr Stylet for 170mm Guide
Type3-v2	3Fr Stylet for 200mm Guide
Type3-v3	4Fr Stylet for 170mm Guide
Type3-v4	4Fr Stylet for 200mm Guide

8. Substantial Equivalence Comparison

The following table compares the Kitazato ET Catheter to the predicate device.

Manufacturer	**Kitazato Corporation**	**Cook Medical, Inc.**	**Device Comparison**
Trade Name	**Kitazato ET Catheter** **K192540**	**Guardia Access Embryo Transfer Catheter Sets** **K173686**	
Indications for Use	Kitazato ET Catheters are intended for ultrasound guided introduction of embryos into the uterine cavity following in vitro fertilization.	Used to place in vitro fertilized (IVF) embryos into the uterine cavity.	The indications for use statements are not identical; however, the intended use of the subject and predicate devices are the same (delivery of embryos into the uterine cavity).
Variations/Models	Type1: Catheter with supporting core and Guide Type2: Catheter with supporting core and Guide with Obturator Type3: Stylet	Catheter and Guide – internal supporting cannula available in one version	**Different:** Both offer transfer and guide catheters. All of the subject devices include an additional internal support, which is comparable to a version of the predicate device. The subject device also includes obturators and stylets. The

Manufacturer	**Kitazato Corporation**	**Cook Medical, Inc.**	**Device Comparison**
Trade Name	**Kitazato ET Catheter** **K192540**	**Guardia Access Embryo Transfer Catheter Sets** **K173686**	
			inclusion of obturators and stylets do not raise different questions of safety and effectiveness.
Design Features	Catheter: Open-end with depth markings, Luer lock hub, with and without echo chip marker; Guide: Precurved, depth marks, styrene elastomer stopper, straight or bulb tip, with and without echo tip	Transfer Catheter: Open-ended with depth markings, Luer lock hub, with and without echo tip; Guide: Precurved, bulb tip, stopper, no depth markings or echo tip	**Different.** Both offer catheter models and guides with the same basic design features. The differences shown do not raise different questions of safety and effectiveness.
Materials	Transfer Catheter - Silicone, stainless steel/polyimide core, ABS, nylon Guide - Nylon, polycarbonate, styrene elastomer, stainless steel Obturator – Nylon, polycarbonate Stylet – Nylon, stainless steel, polycarbonate	Transfer catheter - Polyethylene, polyurethane, stainless steel Guide - Polyurethane, silicone, polymethylpentene	**Different:** Different materials are used in the subject and predicate devices; however, they do not raise different questions of safety and effectiveness.
Sterilization method	Gamma irradiation	Ethylene oxide	**Different:** Different questions of safety and effectiveness are not raised by the use of different sterilization methods.
Single-Use	Yes	Yes	Same
Shelf Life	3 years	3 years	Same
Length of Catheters	Transfer catheter – 22 cm, 25 cm and 40cm Guide catheter – 17 cm, 20 cm	Transfer catheter – 23 - 25 cm Guide catheter – 16.7 cm, 17.3 cm	**Different:** The dimensions are comparable for the majority of the subject devices with the exception of the Type 2 v 5. This version is longer than the predicate devices, but it

Manufacturer	**Kitazato Corporation**	**Cook Medical, Inc.**	**Device Comparison**
Trade Name	**Kitazato ET Catheter** **K192540**	**Guardia Access Embryo Transfer Catheter Sets** **K173686**	
			does not raise different questions of safety and effectiveness as the device can only be inserted the same depth as the other devices. The additional length is provided to allow the physician to be positioned further from the subject during a procedure.
Outer Diameter	Catheter – 1.0mm/3 Fr, 1.35mm/4 Fr Guide – 1.9mm, 2.2mm	Transfer Catheter – 2.8 Fr Guide Catheter – 6.6 Fr	**Different:** The differences in outer diameter between the subject and predicate do not raise different questions of safety and effectiveness.
Depth Markings	Transfer Catheter - located at 1, 2, 3 and 4 cm from connector. Guide catheter marks - located at 4, 5, 6, 7 and 8cm from the tip.	Transfer catheter includes depth marks (spacing not known). No depth markings on Guide catheter.	**Different:** The subject and predicate catheter components include depth markings, while only the subject device Guide catheter includes depth markings. Differences in depth marking between the subject and predicate device do not raise different questions of safety and effectiveness.
Mouse Embryo Assay	1-cell, ≥ 80% blastocyst at 96h	≥ 80%expanded blastocytes within 96 hours	**Similar**
Endotoxin	< 20 EU/device	< 20 EU/device	**Same**

9. Non-Clinical Performance Data

The following studies have been performed to support substantial equivalence to the predicate device:

- Sterilization validation per ISO 11137-1:2006(R)2010 &A1:2013 and ISO 11137-2:2013
- Biocompatibility studies conducted in accordance with ISO 10993-1: 2018 and the 2016 FDA Guidance Document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1:Evaluation and testing within a risk management process*."

  - Cytotoxicity ISO 10993-5:2009
  - Sensitization ISO 10993-10:2010
  - Intracutaneous reactivity ISO 10993-10:2010
- Endotoxin testing per AAMI/ANSI ST72:2011; USP <85> (<20 EU/device)
- Transportation Simulation study per ASTM D4169-16
  - Assessment of packaging and contents after conditioning
  - Bubble leak test per ASTM F2096-11 after conditioning
- Package Integrity testing:
  - Visual Inspection per ASTM F1866/F1886M-09
  - Dye Penetration test per ASTM F1929-15
  - Seal Strength test per ASTM F88/F88M-15
- Mouse Embryo Assay (MEA) before and after aging (1-Cell MEA: ≥80% blastocysts at 96h)
- Bench Performance studies before and after aging demonstrated that all predetermined acceptance criteria were met in the following tests:
  - Dimensional Verification – Devices were measured and verified against device input requirements.
  - Appearance – Devices were visually inspected to ensure that no burrs, scratches, or foreign objects observed.
  - Tensile Strength: Testing demonstrates that the tensile strength value is greater than the pre-determined acceptance criterion.
  - Luer Taper Inspection: Testing is visual inspection to assess connection of the shaft to a 6% tapered female connector.
  - Colorfastness – Testing demonstrates that the depth marking is legible undergoing friction testing (100 rubs at 200 g load weight).
  - Echo Test: Testing demonstrates maintenance of the echo chip band on the catheter and guide in accordance with a pre-determined acceptance criterion.

10. Statement of Substantial Equivalence

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.