DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 13, 2017

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

Re: K162878
Trade/Device Name: Kitazato ET Catheters
Regulation Number: 21 CFR§ 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: II
Product Code: MQF
Dated: June 12, 2017
Received: June 13, 2017

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. 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,

Joyce M. Whang -S

for

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)*
K162878

Device Name
Kitazato ET Catheters

Indications for Use *(Describe)*
The Kitazato ET Catheters are intended for ultrasound guided introduction of embryos into the uterine cavity following in vitro fertilisation.
Kitazato ET Catheters are provided in various configurations (Type 1 through Type 5), which consist of the following components:
• Transfer Catheter, for delivery of embryos into the uterine cavity;
• Guide Catheter, to guide the insertion of the Transfer Catheter and reinforce it during use:
• Trial Catheter, used to confirm the curvature of the cervix and if the cervix is passable;
• Stylet Sheath, used to increase the strength of the Guide Catheter during insertion.

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)

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510(k) Summary

Kitazato ET Catheters

1. Submission Sponsor

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Contact: Audrey Swearingen, RAC (US)
Title: Director, Regulatory Affairs

3. Date Prepared

July 13, 2017

4. Device Identification

Trade/Proprietary Name:	Kitazato ET Catheters
Common/Usual Name:	Embryo Transfer Catheter
Classification Name:	Assisted Reproduction Catheter
Regulation Number:	884.6110
Product Code:	MQF, Assisted Reproduction Catheter

Device Class: Class II

Classification Panel: Obstetrics/Gynecology

5. Legally Marketed Predicate Device(s)

K033084 - Portex, Ltd. Wallace Embryo Replacement Catheters and Trial Transfer Catheters

The predicate device was subject to a design-related recall in 2013. However, the recall status for the predicate device is completed, and the predicate device is currently marketed.

6. Indication for Use Statement

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

Kitazato ET Catheters are provided in various configurations (Type 1 through Type 5), which consist of the following components:

- Transfer Catheter, for delivery of embryos into the uterine cavity;
- Guide Catheter, to guide the insertion of the Transfer Catheter and reinforce it during use;
- Trial Catheter, used to confirm the curvature of the cervix and if the cervix is passable;
- Stylet Sheath, used to increase the strength of the Guide Catheter during insertion.

7. Device Description

Kitazato ET Catheters are sterile, single-use catheters for embryo transfer. The ET Catheters consist of a transfer catheter, guide catheter, trial catheter, and a stylet sheath. The Transfer catheter (hereafter referred to as 'catheter' or 'ET Catheter') is composed of a catheter shaft, a connector and a shaft protective sleeve (protector). The catheter types include a normal catheter (Type1, EC-PRO Normal), a catheter with a stainless outer stiffener (Type2, EC-PRO Supported), a catheter with Echo Line (Type3, EC-PRO Master), and a catheter that has both the stainless outer stiffener and the echo line (Type4, EC-PRO Master Supported), all of which are offered in lengths of 18cm and 23cm, and various versions (v1-v8). A corresponding Trial catheter of the same length is provided for all four Types of the Kitazato ET Catheters. The Guide catheter is offered both with a straight shaft and a 30° pre-curved distal shaft. The Stylet Cannula (Type5) is an optional accessory used when additional rigidity is needed during insertion of the cannula through the cervix, and is offered in two lengths, 13.5 cm and 18.5 cm.

During the implantation procedure of the embryo into the uterus, the catheter is introduced into the uterine cavity through the cervix, then the embryo is delivered into the uterine cavity by plunging the syringe that is coupled at the connector end of the catheter via a 6% taper luer lock. A syringe is not included with the Kitazato ET Catheters.

Model configurations and specifications for the Kitazato ET Catheters (Types 1 – 4) are listed below:

Version	Version Components		
	Catheter	**Guide**	**Trial**
Version 1 (v1)	18 cm ET Transfer Catheter	14 cm Guide Catheter (straight)	n/a
Version 2 (v2)	23 cm ET Transfer Catheter	19 cm Guide Catheter (straight)	n/a
Version 3 (v3)	n/a	14 cm Guide Catheter (straight)	18 cm Trial Catheter
Version 4 (v4)	n/a	19 cm Guide Catheter (straight)	23 cm Trial Catheter
Version 5 (v5)	18 cm ET Transfer Catheter	n/a	n/a
Version 6 (v6)	23 cm ET Transfer Catheter	n/a	n/a
Version 7 (v7)	18 cm ET Transfer Catheter	14 cm Guide Catheter (curved)	n/a
Version 8 (v8)	23 cm ET Transfer Catheter	19 cm Guide Catheter (curved)	n/a

Model configurations and specifications for the Type 5 stylet are listed below:

Type 5-v1	13.5 cm	Used with 14 cm Guide Catheter and 18 cm ET Transfer Catheter
Type 5-v2	18.5 cm	Used with 19 cm Guide Catheter and 23 cm ET Transfer Catheter

8. Substantial Equivalence Discussion

The following tables compare the Kitazato ET Catheters to the predicate devices with respect to indications for use, principles of operation, technological characteristics, materials, and performance. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. Based on the information below, the subject and predicate device have comparable intended uses, and the differences in technology noted do not raise different questions of safety or effectiveness as compared to the predicate.

Table 1 – Comparison of Characteristics

Manufacturer	**Kitazato Corporation**	**Portex, Ltd. (marketed by Smiths Medical**	**Device Comparison**
Trade Name	**Kitazato ET Catheters, Type1, Type2, Type3, Type4, Type5**	**Wallace Embryo Replacement Catheters and Trial Transfer Catheters**	
510(k) Number	K162878	K033084	N/A
Product Code	MQF	MQF	Same
Regulation Number	884.6110	884.6110	Same
Regulation Name	Assisted Reproduction Catheter	Assisted Reproduction Catheter	Same
Indications for Use	The Kitazato ET Catheters are intended for ultrasound guided introduction of embryos into the uterine cavity following in vitro fertilisation. Kitazato ET Catheters are provided in various configurations (Type 1 through Type 5), which consist of the following components: • Transfer Catheter, for delivery of embryos into the uterine cavity; • Guide Catheter, to guide the insertion of the transfer catheter and reinforce it during use; • Trial Catheter, used to confirm the curvature of the cervix and if the cervix is passable; • Stylet Sheath, used to increase the strength of	Embryo Replacement Catheters are sterile, single-use devices for ultrasound guided introduction of embryos into the uterine cavity following in vitro fertilisation. Trial Transfer Catheters are sterile, single-use devices for determining whether the cervix is passable for a Wallace embryo replacement catheter	Similar. The subject and predicate device have the same intended use - ultrasound guided introduction of embryos into the uterine cavity following in vitro fertilisation.

Manufacturer	**Kitazato Corporation**	**Portex, Ltd. (marketed by Smiths Medical**	**Device Comparison**
Trade Name	**Kitazato ET Catheters, Type1, Type2, Type3, Type4, Type5**	**Wallace Embryo Replacement Catheters and Trial Transfer Catheters**	
	the Guide Catheter during insertion.		
Variations	Type1: EC-PRO Normal; Type2: EC-PRO Supported – same as Type1 but with outer stiffener on shaft; Type3: EC-PRO Master - same as Type1 but with pre-marked Echo line on shaft for ultrasound imaging visibility; Type4: EC-PRO Master Supported – includes both outer stiffener and Echo line; Each Type includes catheters of 18cm and 23cm length (v1 and v2) with corresponding Guides, and Trials of the same length (v3 and v4).	Sure View Embryo Replacement Catheter with echogenic shaft for ultrasound imaging visibility; Sure View Trial Transfer Catheters Sure View models include inner catheters of 18cm and 23cm length, with corresponding outer sheath	Different. However, both offer catheter models and guides with the same basic design features. These differences do not raise different questions of safety and effectiveness.
Design Overview	Transfer catheter, Guide catheter, Trial catheter: Transfer Catheter: Open-end shaft with depth marks and protective sleeve, luer connector, outer stiffener (some variations), and echo line (some variations);	Inner catheter (transfer), Outer sheath (guide), Trial catheter: Transfer Catheter: Open-ended shaft with depth markings, luer hub, and echo line.	Similar. The minor differences in the design do not raise different questions of safety and effectiveness.

Manufacturer	**Kitazato Corporation**	**Portex, Ltd. (marketed by Smiths Medical**	**Device Comparison**
Trade Name	**Kitazato ET Catheters, Type1, Type2, Type3, Type4, Type5**	**Wallace Embryo Replacement Catheters and Trial Transfer Catheters**	
	Guide: Straight or curved shaft with depth marks, and handle/ connector; Trial: Identical to corresponding size transfer catheter, but with closed end.	Guide: Shaft with depth marks, and handle/connector; Trial: Same as corresponding size transfer catheter, but with closed end.	
Stylet	Yes (Type 5)	No	Different. However, different questions of safety and effectiveness are not raised by the inclusion of a stylet as it's used to provide additional rigidity to the device.
Materials	Catheter/Trial shaft: Polyurethane; Guide: Fluoric resin; Luer connector: ABS; Outer stiffener: Stainless steel	Shaft: flexible plastic of unknown type; Remaining materials not known	Unknown. However, different questions of safety and effectiveness are not raised, and can be assessed through biocompatibility testing
Sterile	Yes – Ethylene oxide	Yes – Ethylene oxide	Same
Single-Use	Yes	Yes	Same
Catheter Length	18 cm and 23 cm	18 cm and 23 cm	Same
Catheter Outer Diameter	Catheter - 1.55 mm / 4.7 Fr	Inner Catheter - 1.52 mm	Similar
Depth Markings	Yes	Yes	Same
Guide Length	14cm and 19cm	Unknown (expected to be 13 and 18cm, based on available information)	Similar
Ultrasound Visible	Yes (Type3 and Type4)	Yes	Same

Manufacturer	**Kitazato Corporation**	**Portex, Ltd. (marketed by Smiths Medical**	**Device Comparison**
Trade Name	**Kitazato ET Catheters, Type1, Type2, Type3, Type4, Type5**	**Wallace Embryo Replacement Catheters and Trial Transfer Catheters**	
Mouse Embryo Assay	1-cell, ≥ 80% expanded blastocysts at 96 hrs	2-cell, ≥ 80% blastocyst	Similar
Endotoxin	< 20 EU/device	<0.5 EU/ml	Same

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the Kitazato ET Catheters and in showing substantial equivalence to the predicate devices, Kitazato completed a number of non-clinical tests. The device meets all the requirements for design, sterilization, biocompatibility, and functionality.

The Kitazato ET Catheters passed all the testing in accordance with internal requirements, national standards, and international standards support substantial equivalence:

- Biocompatibility Testing per ISO 10993-1:2009 and 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 Extraction Method, ISO 10993-5:2009)
    - Sensitization (ISO Guinea Pig Maximization Sensitization, ISO 10993-10:2010)
    - Irritation (ISO Intracutaneous Reactivity Test, ISO 10993-10:2010)
- Mouse Embryo Assay (MEA)
    - 1-Cell mouse embryos were incubated in extracts of the subject device at 37°C in an atmosphere containing 5% CO_2. The percent of embryos developed to the expanded blastocyst stage at 96 hours were assessed in comparison with the control group. The acceptance criterion was 1-Cell MEA: ≥80% expanded to blastocyst at 96 hours.
- Endotoxin Testing per ANSI/AAMI ST72:2011: Endotoxin values conform to the specification of ≤20 EU/device
- Sterilization validation per ISO 11135:2014 and ISO 10993-7:2008
- Dimensional Verification – final sterile devices confirmed to the dimensional specifications, and luer connectors conform to requirements of ISO 594-1 and ISO 594-2.
- Appearance Testing - passes visual inspection for scratches, burrs, and foreign objects
- Mechanical Tensile Testing (shaft and strength between shaft and connector) – Tensile strength met the established specifications.

- Depth Mark color-fastness testing per JIS L 0849 / JIS L 0803 – The ink depth markings remained clearly legible after soaking in saline for 24 hours and undergoing 100 cycles of rubbing.

- Package Integrity Testing per ISO 11607-1:2006(R)2014, *Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging systems* and ISO 11607-2:2006, *Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing, and Assembly Processes*: passed dye penetration, seal strength, and visual inspection per ASTM 1929-15, ASTM 1866/F 1886M-09, and ASTM F88/F88M-15.

- Transport Testing per ASTM D4169-09 – Packaging maintained device integrity.

- Shelf Life Testing – Established three (3) year shelf life following real time aging. The following parameters were assessed during shelf life testing: tensile strength, dimension, appearance, sterility, endotoxin, MEA, and color fastness.

10. Statement of Substantial Equivalence

The results of the performance testing described above demonstrate that the Kitazato ET Catheters are as safe and effective as the predicate device and supports a determination of substantial equivalence.