DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 11, 2017

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

Re: K162667
Trade/Device Name: Kitazato IUI Catheter
Regulation Number: 21 CFR§ 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: II
Product Code: MQF
Dated: April 13, 2017
Received: April 14, 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,

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)*
K162667

Device Name
Kitazato IUI Catheter

Indications for Use *(Describe)*
Kitazato IUI Catheter consists of the following versions:

• Kitazato IUI Catheter with Outer Stiffener with or without Stylet Cannula, 18 cm, model number Type 4-v1 and Type 4-v2
• Kitazato IUI Catheter with Outer Stiffener with or without Stylet Cannula, 10 cm, model number Type 4-v3 and Type 4-v4
• Kitazato IUI Catheter with Outer Stiffener with Stainless Steel Core, 18 cm, model number Type 5-v1 and Type 5-v2
• Kitazato IUI Catheter with Outer Stiffener with Stainless Steel Core, 10 cm, model number Type 5-v3 and Type 5-v4

Kitazato IUI Catheter is used for the introduction of washed spermatozoa into the uterine cavity through the cervix.
Kitazato IUI Stylet is used to provide rigidity and assist in maintaining the shape of the catheter shaft.

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 IUI Catheter

K162667

1. Submission Sponsor

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3. Date Prepared

May 10, 2017

4. Device Identification

Trade/Proprietary Name:	Kitazato IUI Catheter
Common/Usual Name:	Intrauterine Insemination (IUI) Catheter
Classification Name:	Assisted Reproduction Catheters
Classification Number:	884.6110

Product Code:	MQF, Assisted Reproduction Catheter
Device Class:	Class II
Classification Panel:	Obstetrics/Gynecology

5. Legally Marketed Predicate Device(s)

K131491, Kitazato IUI Catheter, KITAZATO Medical Co., Ltd.

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

6. Indication for Use Statement

Kitazato IUI Catheter consists of the following versions:

- Kitazato IUI Catheter with Outer Stiffener with or without Stylet Cannula, 18 cm, model number Type 4-v1 and Type 4-v2
- Kitazato IUI Catheter with Outer Stiffener with or without Stylet Cannula, 10 cm, model number Type 4-v3 and Type 4-v4
- Kitazato IUI Catheter with Outer Stiffener with Stainless Steel Core, 18 cm, model number Type 5-v1 and Type 5-v2
- Kitazato IUI Catheter with Outer Stiffener with Stainless Steel Core, 10 cm, model number Type 5-v3 and Type 5-v4

Kitazato IUI Catheter is used for the introduction of washed spermatozoa into the uterine cavity through the cervix.
Kitazato IUI Stylet is used to provide rigidity and assist in maintaining the shape of the catheter shaft.

7. Device Description

The Kitazato IUI Catheter is a set of intrauterine insemination (IUI) catheters comprised of two different models that include either no stainless steel core (Type 4) or a stainless steel core (Type 5). Each type of catheter has a 10 cm or 18 cm catheter shaft length that incorporates an outer stiffener component and a syringe connector. The distal tip of the catheter shaft is rounded and includes two side holes 3 mm from the tip of the catheter for sperm delivery. The catheter shaft also includes depth marker bands at 5, 6, 7, and 8 cm from the distal tip to aid in delivery of the device to the targeted depth.

The catheter is composed of a polyvinyl chloride shaft and an acrylonitrile butadiene styrene (ABS) connector. The Stylet Cannula (Type 6) used with the Type 4 catheter is composed of a stainless steel cannula (SUS304) and an ABS syringe connector. The Stylet Cannula's stainless steel core provides rigidity and assists in maintaining the shape of the catheter shaft when the uterine cervix is sharply curved. The Stylet Cannula is inserted into the catheter shaft through the connector end and then the IUI Catheter is inserted into the cervix. During an IUI procedure, the catheter is introduced into the uterine cavity through the cervix, and the spermatozoa are injected into the uterine cavity by a syringe (not included) that is coupled at the connector end (6% taper connection) of the catheter shaft.

Model configurations and specifications for the Kitazato IUI Catheters are listed below:

Code	Model	Product Code Name	Catheter Body	Center Core Material	Catheter Length	Outer Diameter	Depth mark	Stylet Cannula
131184	Type4-v1	Catheter with Outer Stiffener with Stylet Cannula	Polyvinyl-chloride (not made with DEHP)	None	18 cm	1.70mm/5 Fr	Yes	Yes
131182	Type4-v2			None	18 cm	2.00mm/6Fr	Yes	Yes
131104	Type4-v3			None	10 cm	1.70mm/5 Fr	Yes	Yes
131102	Type4-v4			None	10 cm	2.00mm/6Fr	Yes	Yes
131181	Type5-v1	Catheter with Outer Stiffener with Stainless Steel Core	Polyvinyl-chloride (not made with DEHP)	S.S. SUS 304	18 cm	2.00mm/6Fr	Yes	No
131186	Type5-v2			S.S. SUS 304	18 cm	2.00mm/6Fr	Yes	No
131101	Type5-v3			S.S. SUS 304	10 cm	2.00mm/6Fr	Yes	No
131106	Type5-v4			S.S. SUS 304	10 cm	2.00mm/6Fr	Yes	No
140918	Type6-v1	Stylet cannula	n/a	S.S. SUS 304	18 cm	0.65 mm	n/a	n/a
140118	Type6-v2			S.S. SUS 304	10 cm	0.65 mm	n/a	n/a

8. Substantial Equivalence Discussion

The following table compares the Kitazato IUI Catheter to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. 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**	**KITAZATO Medical Co., Ltd.**	**Significant Differences**
Trade Name	**Kitazato IUI Catheter**	**Kitazato IUI Catheter Type 3 with Outer Stiffener with Stylet Cannula**	
510(k) Number	K162677	K131491	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	Kitazato IUI Catheter consists of the following	Kitazato IUI Catheter consist	Different. The Stylet is not included separately

Manufacturer	**KITAZATO Corporation**	**KITAZATO Medical Co., Ltd.**	**Significant Differences**
Trade Name	**Kitazato IUI Catheter**	**Kitazato IUI Catheter Type 3 with Outer Stiffener with Stylet Cannula**	
	versions: • Kitazato IUI Catheter with Outer Stiffener with or without Stylet Cannula, 18 cm, model number Type 4-v1 and Type 4-v2 • Kitazato IUI Catheter with Outer Stiffener with or without Stylet Cannula, 10 cm, model number Type 4-v3 and Type 4-v4 • Kitazato IUI Catheter with Outer Stiffener with Stainless Steel Core, 18 cm, model number Type 5-v1 and Type 5-v2 • Kitazato IUI Catheter with Outer Stiffener with Stainless Steel Core, 10 cm, model number Type 5-v3 and Type 5-v4 Kitazato IUI Catheter is used for the introduction of washed spermatozoa into the uterine cavity through the cervix. Kitazato IUI Stylet is used to provide rigidity and assist in maintaining the shape of the catheter shaft.	of the following versions: • Kitazato IUI Catheter with Outer Stiffener with Stylet Cannula**,** 18 cm, model number Type 3-v1 • Kitazato IUI Catheter with Outer Stiffener without Stylet Cannula, 18 cm, model number Type 3-v2 Kitazato IUI Catheter is used for the introduction of washed spermatozoa into the uterine cavity through the cervix.	in the indications for use statement of the predicate device. However, the inclusion of a stylet does not represent a new intended use.
Overall Design	The device consists of types of IUI catheters with an outer stiffener with no stainless steel core (Type 4), outer stiffener with stainless steel core (Type 5),	The device consists of types of IUI catheters with an outer stiffener with and without a stylet cannula (Type 3). The catheter has a smooth distal tip and two	Different; the subject device includes a version of the IUI catheter that utilizes a stainless steel core. The inclusion of this stainless steel core

Manufacturer	**KITAZATO Corporation**	**KITAZATO Medical Co., Ltd.**	**Significant Differences**
Trade Name	**Kitazato IUI Catheter**	**Kitazato IUI Catheter Type 3 with Outer Stiffener with Stylet Cannula**	
	and stylet cannula for Type 4 catheters. The catheter has a smooth distal tip with two side holes. All types have a syringe connector hub compatible with a 6% taper syringe (not included). The catheters are packaged in a barrier sterilization package.	side holes. All types have a syringe connector hub compatible with a 6% taper syringe (not included). The catheters are packaged in a barrier sterilization package.	does not raise different questions of safety or effectiveness.
Sterile	Ethylene Oxide (EO)	Radiation	Different; however Differences in the sterilization method do not raise different questions of safety and effectiveness.
Single-Use	Yes	Yes	Same
French Size	Type 4 (catheter shaft): 1.7 mm / 5 Fr 2 mm / 6 Fr Type 5 (catheter shaft): 2 mm / 6 Fr Outer stiffener shaft of catheter: 2.5 mm / 7.5 Fr	Catheter shaft 2 mm / 6 Fr Outer stiffener shaft 2.5 mm/ 7.5 Fr	Similar
Length	10 and 18 cm	18 cm	Different; However, no different questions of safety and effectiveness are raised due to a shorter length of the subject device.
Depth Marks	Centimeter marks are located at 5, 6, 7, 8 cm from tip on the outer stiffer	Centimeter marks are located at 5, 6, 7, 8 cm from tip on the outer stiffer	Same
Tip	Closed and smoothly rounded; two side holes end type	Closed and smoothly rounded; two side holes end type	Same
Stainless steel core	Type 4: No	No	Different; the Type 5

Manufacturer	**KITAZATO Corporation**	**KITAZATO Medical Co., Ltd.**	**Significant Differences**
Trade Name	**Kitazato IUI Catheter**	**Kitazato IUI Catheter Type 3 with Outer Stiffener with Stylet Cannula**	
	Type 5: Yes		version of the subject device contains a stainless steel core. However, no different questions of safety and effectiveness are raised by this inclusion.
Stylet	Type 4: Yes Type 5: No	Yes	Different; the Type 5 model does not utilize the optional Type 6 stylet cannula. However, an internal stainless steel core is present to provide additional rigidity during insertion. No different questions of safety and effectiveness are raised.
Stylet length	10 and 18 cm	18 cm	Different; however, no different questions of safety and effectiveness are raised due to the shorter length.
Stylet width	0.65 mm	0.65 mm	Same
Materials	Polyvinyl chloride, ABS, stainless steel	Polyvinyl chloride, ABS, stainless steel	Same
Biocompatible per ISO 10993-1	Yes	Yes	Same
HSSA	≥ 70% motility at 24 hours	≥ 70% motility at 24 hours	Same
Endotoxin	<20 EU/device	<20 EU/device	Same

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the Kitazato IUI Catheter that are subject to this 510(k) submission and in showing substantial equivalence to the predicate device, Kitazato Corporation completed a number of non-clinical performance tests.

The Kitazato IUI Catheter passed all the testing as shown below to support substantial equivalence to the subject device:

- Mechanical Tensile Testing: Tensile strength of the shaft and connector passed the established specifications
- Dimensional Testing: Passes outer diameter and length according to specifications
- Appearance Testing: Passes visual inspection for scratches, burrs, and foreign objects
- Endotoxin Testing per ANSI/AAMI ST72:2002/(R)2010: Endotoxin values conform to the specification of ≤20 EU/device
- Sterility Testing per USP <71>: No microbial growth
- 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

  The subject device passed testing for cytotoxicity, intracutaneous reactivity, and sensitization.
- Human Sperm Survival Assay (HSSA): ≥70% motility at 24 hours
- Color fastness of the depth marker bands: no change in appearance of depth marks following conditioning
- 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, HSSA, and color fastness.
- 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.

10. Statement of Substantial Equivalence

The results of the performance testing described above demonstrate that the Kitazato IUI Catheter is as safe and effective as the predicate device and supports a determination of substantial equivalence.