DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 11, 2017

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

Re: K162881
Trade/Device Name: Kitazato OPU Needles
Regulation Number: 21 CFR§ 884.6100
Regulation Name: Assisted Reproduction Needles
Regulatory Class: II
Product Code: MQE
Dated: June 2, 2017
Received: June 2, 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)*
K162881

Device Name
Kitazato OPU Needles

Indications for Use *(Describe)*
The Kitazato OPU Needles consisting of:

- Kitazato OPU Needle with Connection Tube (model number Type2)
- Kitazato OPU Reduced Needle (model number Type3)
- Kitazato OPU Two-Stage Reduced Needle (model number Type4)

are intended to obtain oocytes from ovarian follicles.

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 OPU Needles – K162881

1. Submission Sponsor

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2. Submission Correspondent

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Contact: Audrey Swearingen, RAC
Title: Director, Regulatory Affairs

3. Date Prepared

July 7, 2017

4. Device Identification

Trade or Proprietary Name:	Kitazato OPU Needles
Common or Usual Name:	Oocyte aspiration needle
Regulation Number:	884.6100
Regulation Name:	Assisted Reproduction Needles
Product Code:	MQE
Product Code Name:	Needles, Assisted Reproduction
Class of Device:	Class II
Panel:	Obstetrics/Gynecology

5. Legally Marketed Predicate Device(s)

KITAZATO Medical Co., Ltd., K112492, Kitazato OPU Needle with Connection Tube, Type2 and Kitazato OPU Reduced Needle, Type 3.

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

6. Indication for Use Statement

The Kitazato OPU Needles consisting of:

- Kitazato OPU Needle with Connection Tube (model number Type2)
- Kitazato OPU Reduced Needle (model number Type3)
- Kitazato OPU Two-Stage Reduced Needle (model number Type4)

are intended to obtain oocytes from ovarian follicles.

7. Device Description

The Kitazato OPU Needles are single-use sterile devices that are used for ultrasound-guided trans-vaginal collection of oocytes from ovarian follicles.

All of the Kitazato OPU Needle have a similar general design and device materials. All of the Kitazato OPU Needles are composed of a 304 stainless steel needle, acrylonitrile butadiene styrene (ABS) needle hub, PVC connection tube, and a silicone stopper that is used to connect to a collection tube and vacuum pump.

The Type2 OPU Needles consist of straight aspiration needles (no tapering) with the following characteristics:

Model	Color of Hub	Needle O.D. (mm)	Needle Gauge	Needle Length (mm)	Needle ID (mm)	Wall Thickness (mm)	Needle Bevel Angle	Connection Tube Length (mm)	Connection Tube O.D. (mm)	Connection Tube ID (mm)	Stopper Size	Tube size Compatible with Stopper
Type2 v1/-v10	White	1.65	16	350	1.19	0.23	14°	800, 1000	2.0	1.4	2.5	1.4 (2.5)
Type2 – v2/v11	Light brown	1.49	17	350	1.06	0.22	14°	800, 1000	2.0	1.4	2.5	1.4 (2.5)
Type2 – v3/v12	Pink	1.25	18	350	0.86	0.20	14°	800, 1000	2.0	1.2	2.5	1.2 (2.5)
Type2 – v4/v13	Ivory	1.06	19	350	0.74	0.16	14°	800, 1000	2.0	1.0	2.5	1.0 (2.5)
Type2 – v5/v14	Yellow	0.90	20	350	0.64	0.13	14°	800, 1000	2.0	1.2	2.5	1.2 (2.5)
Type2 – v6/v15	Yellow	0.90	20	300	0.64	0.13	14°	800, 1000	2.0	1.2	2.5	1.2 (2.5)
Type2 – v7/v16	Green	0.80	21	300	0.54	0.13	14°	800, 1000	2.0	1.2	2.5	1.2 (2.5)
Type2 – v8/v17	Black	0.70	22	300	0.43	0.13	14°	800, 1000	2.0	1.2	2.5	1.2 (2.5)
Type2 – v9/v18	Light blue	0.63	23	300	0.39	0.12	14°	800, 1000	2.0	1.0	2.5	1.0 (2.5)

The Type3 OPU Needles consist of aspiration needles with a tapered tip over the distal 40 or 100 mm of the tip. The table below shows the features of the Type3 OPU Needles:

Model	Color of Hub	Needle O.D. (mm) M: main T: Tapered O.D.	Needle Gauge M: main T: Tapered Gauge	Needle Length (mm) TL: Tapered Length	Needle ID (mm) M: main T: Tapered I.D.	Wall Thickness (mm)	Needle Bevel Angle	Connection Tube Length (mm)	Connection Tube O.D. (mm)	Connection Tube ID (mm)	Stopper Size	Tube size Compatible with Stopper
Type3 -v1	Green	M 1.25 T 0.80	M 18 T 21	300, 325 350 TL-40	M-0.86 T-0.54	0.195 T-0.13	14°	800, 1000	2.0	1.2	2.5	1.2 (2.5)
Type3 -v2	Black	M 1.25 T 0.70	M 18 T 22	300, 325 350 T-40	M-0.86 T-0.45	0.195 T-0.13	14°	800, 1000	2.0	1.2	2.5	1.2 (2.5)
Type3 -v3	Light Blue	M 1.25 T 0.63	M 18 T 23	300, 325 T-40	M-0.86 T-0.43	0.195 T-0.10	14°	800, 1000	2.0	1.2	2.5	1.2 (2.5)
Type3 -v4	Ivory	M 1.49 T 1.06	M 17 T 19	300, 325 350 T-100	M-1.20 T-0.78	0.145 T-0.14	14°	800, 1000	2.0	1.4	2.5	1.4 (2.5)
Type3 –v5	Yellow	M 1.49 T 0.90	M 17 T 20	300, 325 350 T-100	M-1.20 T-0.62	0.145 T-0.14	14°	800, 1000	2.0	1.4	2.5	1.4 (2.5)

Type3 –v6	Green	M 1.25 T 0.80	M 18 T 21	300, 325 T-100	M-0.86 T-0.54	0.195 T-0.13	14°	800, 1000	2.0	1.2	2.5	1.2 (2.5)
Type3 –v7	Black	M 1.25 T 0.70	M 18 T 22	300, 325 T-100	M-0.86 T-0.45	0.195 T-0.13	14°	800, 1000	2.0	1.2	2.5	1.2 (2.5)
Type3 –v8	Light Blue	M 1.25 T 0.63	M 18 T 23	300, 325 T-100	M-0.86 T-0.43	0.195 T-0.10	14°	800, 1000	2.0	1.2	2.5	1.2 (2.5)

The Type4 OPU Needles consist of aspiration needles that taper at two locations at the distal tip of the device, with the first taper beginning 70 mm from the tip and the second starting 25 mm from the tip. The table below shows the features of the Type4 OPU Needles.

Model	**Color of Hub**	**Needle O.D. (mm)** **M**: main **T1:** 1st Step Tapered **T2 :** 2nd Step Tapered	**Needle Gauge** **M**: main **T1:** 1st Step Tapered **T2:** 2nd Step Tapered	**Needle Length (mm)** **M:** main **T1:** 1st Step Tapered **T2 :** 2nd Step Tapered	**Needle ID (mm)** **M:** main **T2:** 2nd Step Tapered	**Wall Thickness (mm)**	**Needle Bevel Angle**	**Connection Tube Length (mm)**	**Connection Tube O.D. (mm)**	**Connection Tube ID (mm)**	**Stopper Size**	**Tube size Compatible with Stopper**
Type4 –v1	Green	M-1.25 T1-1.06 T2-0.80	M-18/ T1-19, T2-21	M-300 T1-70 T2-25	M-0.98 - T2-0.54	0.135 - 0.13	14°	800, 1000	2.0	1.2	2.5	1.2 (2.5)
Type4 –v2	Black	M-1.25 T1-0.90 T2-0.70	M 18/ T1-20 T2-22	M 300 T1-70 T2-25	M-0.98 - T2-0.43	0.135 - 0.13	14°	800, 1000	2.0	1.2	2.5	1.2 (2.5)
Type4 –v3	Light Blue	M-1.25 T1-0.80 T2-0.63	M-18/ T1-21 T2-23	M-300 T1-70 T2-25	M-0.98 - T2-0.39	0.135 - 0.12	14°	800, 1000	2.0	1.2	2.5	1.2 (2.5)

8. Substantial Equivalence Discussion

The following table compares the indications for use for the subject Kitazato OPU Needles and the predicate device:

Subject Device K162881	**Predicate Device K112462**	**Comments**
The Kitazato OPU Needles consisting of: • Kitazato OPU Needle with Connection Tube (model number Type2) • Kitazato OPU Reduced Needle (model number Type3) • Kitazato OPU Two-Stage Reduced Needle (model number Type4) are intended to obtain oocytes from ovarian follicles.	The Kitazato OPU Needles consisting of: • Kitazato OPU Needle with Connection Tube (model number Type2) • Kitazato OPU Reduced Needle (model number Type3) are intended to obtain oocytes from ovarian follicles.	The intended use of the subject and predicate devices is the same.

The following tables compare the technological characteristics of the subject Kitazato OPU Needles to the predicate devices:

Type2 OPU Needle Technological Characteristics Comparison

Parameter	Subject Device Type2 -OPU Needle With Connection Tube K162881	Predicate Device Type2 -OPU Needle With Connection Tube K112462	Comments
Lumen Type	Single	Single	Same
Tapered Needle	No	No	Same
Device Materials	Stainless steel (304) ABS PVC Silicone Polypropylene Epoxy resin	Stainless steel (304) ABS PVC Silicone Polypropylene Epoxy resin	Same
Needle Gauge Range	16-23	16-24	Similar: The range of needle gauges for the subject devices is within those of the predicate devices.
Needle OD Range	0.63-1.65 mm	0.55 -1.65 mm	Similar: The range of needle ODs for the subject devices is within the range of the predicates.
Needle Length Range	300-350 mm	200-350 mm	Different: The predicate devices are offered in additional sizes that are not available for the subject devices. These differences do not raise different questions of Safety and Effectiveness (S&E) as the range of needle lengths for the subject devices is within the range of the predicates.
Echogenic Marker	Yes	Yes	Same
Connection Tube Length	800-1000 mm	200-1000 mm	Different: The predicate devices are offered in additional sizes that are not available for the subject devices. These differences do not raise different questions of S&E as the range of tubing lengths for the subject devices are within the range of the predicates.
Connection Tube OD	2.0	2.0	Same
Connection Tube Fitting	Silicone stopper with attached female connector for aspiration	Silicone stopper with attached female connector for aspiration	Same
Sterilization Method	Ethylene oxide	Gamma radiation	Different – Both are accepted methods for sterilization of ART devices and do not raise different questions of S&E as compared to the

			predicate devices.
Single-Use/Repeat-Use	Single-Use	Single-Use	Same
MEA	1-Cell MEA: ≥80% expanded blastocysts at 96h	1-Cell MEA: ≥80% expanded blastocysts at 96h	Same
Endotoxin	<20 EU/device	<20 EU/device	Same

Type3 OPU Needle Technological Characteristics Comparison

Parameter	Subject Device Type3 -OPU Reduced Needle K162881	Predicate Device Type3 -OPU Reduced Needle K112462	Comments
Lumen Type	Single	Single	Same
Tapered Needle	Yes - single	Yes - single	Same
Device Materials	Stainless steel (304) ABS PVC Silicone Polypropylene Epoxy resin	Stainless steel (304) ABS PVC Silicone Polypropylene Epoxy resin	Same
Needle Gauge Range Main Needle Tapered End	 17-18 19-23	 18 21-23	Different: The range of needle gauges for the subject devices is wider than those for the predicate devices. These differences do not raise different S&E questions as compared to the predicate devices.
Needle OD Range Main Needle Tapered End	 1.25-1.49 mm 0.63-1.06	 0.55 -1.65 mm Not provided in predicate	Different: The range of ODs for the predicate devices is wider than those for the subject devices. These differences do not raise different questions of S&E as all diameters of the subject devices are within the range of ODs of the predicate submission.
Needle Length Range	300-350 mm	200-350 mm	Different: The predicate devices are offered in additional sizes that are not available for the subject devices. These differences do not raise different questions of S&E as the range of needle lengths for the subject devices are within the range of the predicates.
Taper Length	40-100 mm	40-60 mm	Different: The subject devices are offered with a longer taper length than the predicates. These differences do not raise different questions of S&E as compared to

			the predicate devices.
Echogenic Marker	No	No	Same
Connection Tube Length	800-1000 mm	200-1000 mm	Different: The predicate devices are offered in additional sizes that are not available for the subject devices. These differences do not raise different questions of S&E as the range of needle lengths for the subject devices are within the range of the predicates.
Connection Tube OD	2.0	2.0	Same
Connection Tube Fitting	Silicone stopper with attached female connector for aspiration	Silicone stopper with attached female connector for aspiration	Same
Sterilization Method	Ethylene oxide	Gamma radiation	Different – Both are accepted methods for sterilization of ART devices and do not raise different questions of S&E as compared to the predicate devices.
Single-Use/Repeat-Use	Single-Use	Single-Use	Same
MEA	1-Cell MEA: ≥80% expanded blastocysts at 96h	1-Cell MEA: ≥80% expanded blastocysts at 96h	Same
Endotoxin	<20 EU/device	<20 EU/device	Same

Type4 Technological Characteristics Comparison

Parameter	**Subject Device Type4 -OPU Two-Stage Reduced Needle K162881**	**Predicate Device Type3 -OPU Reduced Needle K112462**	**Comments**
Lumen Type	Single	Single	Same
Tapered Needle	Yes - double	Yes - single	Different: The subject devices taper at two points (25 and 70 mm from the tip), while the predicates only have a single taper occurring between 40 and 60 mm from the tip. Dual vs. single tapering does not raise different questions of S&E.
Device Materials	Stainless steel (304) ABS PVC Silicone Polypropylene	Stainless steel (304) ABS PVC Silicone Polypropylene	Same

	Epoxy resin	Epoxy resin	
Needle Gauge Range Main Needle Tapered End	 18 21-23	 18 21-23	Same
Needle OD Range Main Needle Tapered End	 1.25 mm 0.63-0.80 mm	 0.55 -1.65 mm Not in prior submission	Different: The range of ODs for the predicate devices is wider than the ODs for the subject devices. These differences do not raise different questions of S&E as all diameters of the devices in the subject submission are within the range of ODs of the predicates.
Needle Length Range	300	200-350 mm	Different: The predicate devices are offered in additional sizes that are not available for the subject devices. These differences do not raise different questions of S&E as the range of needle lengths for the subject devices are within the range of the predicates.
Echogenic Marker	No	No	Same
Connection Tube Length	800-1000 mm	200-1000 mm	Different: The predicate devices are offered in additional sizes that are not available for the subject devices. These differences do not raise different questions of S&E as the range of needle lengths for the subject devices are within the range of the predicates.
Connection Tube OD	2.0	2.0	Same
Connection Tube Fitting	Silicone stopper with attached female connector for aspiration	Silicone stopper with attached female connector for aspiration	Same
Vacuum Line Provided	No	No	Same
Sterilization Method	Ethylene oxide	Gamma radiation	Different – Both are accepted methods for sterilization of ART devices and do not raise different questions of S&E as compared to the predicate devices.
Single-Use/Repeat-Use	Single-Use	Single-Use	Same
MEA	1-Cell MEA: ≥80% expanded blastocysts at 96h	1-Cell MEA: ≥80% expanded blastocysts at 96h	Same

Endotoxin	<20 EU/device	<20 EU/device	Same

As noted in the tables above, there are many similarities between the subject and predicate devices (e.g., materials, designs, etc.); however, differences do exist. The differences in technology noted in the tables above, do not raise different questions of safety or effectiveness as compared to the predicate device.

9. Non-Clinical Performance Data

As part of demonstrating substantial equivalence to the predicate device, the following non-clinical performance tests were conducted. The Kitazato OPU Needles passed all of the testing in accordance with internal requirements and applicable standards to support substantial equivalence of the subject device:

- Endotoxin testing per ANSI/AAMI ST72-2011: ≤20 EU/device
- 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.
- Sterilization validation per ISO 11135:2014 and ISO 10993-7:2008
- Package integrity testing following real-time aging:
    - Dye penetration testing per ASTM F929-15
    - Seal strength testing per ASTM F88/F88M-15
- Transport testing per ASTM D4169-09
- Shelf-life studies (real-time aged devices) were conducted to ensure that the following product specifications were met to support a three-year shelf-life:
    - MEA
    - Endotoxin
    - Tensile testing (needle to hub and tubing to hub)
    - Bending elasticity of needle – Return to normal position after bending 8**°** from straight
    - Folding strength of needle - No fracture of needle when folded at a 5 mm curvature radius to 90**°**
    - Device appearance (burrs, scratches, damage)
    - Dimensional assessments
- Aspiration pressure testing – Testing involved aspirating water through needles at the recommended aspiration pressures included in device labeling to ensure that devices operated as intended (i.e., no signs of deformation, blockages or damage)
- Biocompatibility testing was conducted according to ISO 10993-1- 2009. Testing included cytotoxicity (ISO 10993-5:2009), intracutaneous reactivity (ISO 10993-10:2010), and 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.

10. Conclusion

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