K112462
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510(k) Summary

For

NOV 26 2012

Kitazato OPU Needle

1. Submission Sponsor

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2. Submission Correspondent

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3. Date Prepared

21 November 2012

4. Device Name

Trade/Proprietary Name:	Kitazato OPU Needle with Connection Tube, model number Type 2 Kitazato OPU Reduced Needle, model number Type 3
Common/Usual Name:	OPU Needle
Classification Name:	Assisted Reproduction Needles
Classification Regulation:	884.6100
Classification Panel:	Obstetrics/Gynecology
Product Code:	MQE
Device Class:	II

5. Predicate Devices

Vitrolife Sweden AB – Follicle Aspiration Set, Reduced Single Lumen (K082727)
Swemed Lab International AB – Swemed Follicle Aspiration Set, Double Lumen, Single Lumen, and Luer Needle (K991273)

6. Device Description

The Kitazato OPU Needles are intended to puncture into the vaginal wall and obtain oocytes from ovarian follicles. The OPU Needle with Connection Tube, model number Type 2, product consists of Aspiration Needle with Connection Tube and Silicone Stopper Connector. The OPU Reduced Needle, model number Type 3, product consists of Reduced Aspiration Needle with Connection Tube and Silicone Stopper Connector.

The OPU Needle with Connection Tube, model number Type 2, includes the following models:

Model	Color of Hub	Needle O.D. (mm)	Needle Gauge	Needle Length (mm)	Connection Tube Length (mm)
Type2 -v1	White	1.65	16	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000
Type2 -v2	Light brown	1.49	17	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000
Type2 -v3	Pink	1.25	18	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000
Type2 -v4	Ivory	1.06	19	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000
Type2 -v5	Yellow	0.90	20	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000
Type2 -v6	Green	0.80	21	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000
Type2 -v7	Black	0.70	22	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000
Type2 -v8	Light blue	0.63	23	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000
Type2 -v9	Purple	0.55	24	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000

The OPU Reduced Needle, mode number Type 3, includes the following models:

Model	Needle Gauge	Needle O.D. (mm)	Narrow Tip Gauge	Narrow Tip O.D. (mm)	Needle Length (mm)	Color of Hub	Length of Reduced Needle (mm)	Connection Tube Length (mm)
Type3 -v1	18	1.25	21	0.80	200, 225, 250, 275, 300, 325, 350	Green	40-60	800
Type3 -v2	18	1.25	22	0.70	200, 225, 250, 275, 300, 325, 350	Black	40-60	800
Type3 -v3	18	1.20	23	0.63	200, 225, 250, 275, 300, 325, 350	Light blue	40-60	800

7. Intended Use

The Kitazato OPU Needles consisting of:

- Kitazato OPU Needle with Connection Tube, model number Type 2
- Kitazato OPU Reduced Needle, model number Type 3

are intended to obtain oocytes from ovarian follicles.

8. Substantial Equivalence Discussion

The indication for use and technology of the OPU Needle are substantially equivalent to the identified predicate devices.

9. Non-Clinical Testing

The needle mechanical tensile testing and mouse embryo testing results supports that all the specifications have met the acceptance criteria for the device. The Kitazato OPU Needles passed all testing and supports the claims of substantial equivalence.

- Mechanical Tensile Testing: Tensile strength to withstand 22N for needle tube O.D. <0.55 mm
- Bending Elasticity Testing: Return normal position after bending 8° from straight for needle tube O.D. ≤1.0 mm
- Folding Strength Testing: No fracture of needle tube is detected when needle tube of O.D. ≤1.0 mm and length ≥12mm is folded to 90°
- Dimensional Testing: Passes outer diameter and length according to specifications
- Endotoxin Testing: Endotoxin values conform to the value ≤20 EU/device
- Sterility Testing: No microbial growth from sterility testing
- Mouse Embryo Assay: ≥80% expanded to blastocyst stage within 96 hours

The Kitazato OPU Needles were tested and complies with the applicable voluntary standards for biocompatibility and sterilization. The device passed all the testing in accordance with national and international standards.

10. Conclusion

The Kitazato OPU Needles are substantially equivalent to its proposed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 26, 2012

KITAZATO Medical Co., Ltd.
% Richard Vincins, CQA, CBA, RAC (US,EU)
Vice President, Quality Assurance
Emergo Group
611 West 5th Street, Third Floor
AUSTIN TX 78701

Re: K112462
Trade/Device Name: Kitazato OPU Needle
Regulation Number: 21 CFR§ 884.6100
Regulation Name: Assisted reproduction needles
Regulatory Class: II
Product Code: MQE
Dated: November 6, 2012
Received: November 15, 2012

Dear Mr. Vincins:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Herbert R. Lerner

-Acting Director 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

Section 4 - Indications for Use Statement

510(k) Number (if known): K112462

Device Name: Kitazato OPU Needle

Indications for Use:

The Kitazato OPU Needles consisting of:

- Kitazato OPU Needle with Connection Tube, model number Type 2

Model	Color of Hub	Needle O.D. (mm)	Needle Gauge	Needle Length (mm)	Connection Tube Length (mm)
Type2 -v1	White	1.65	16	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000
Type2 -v2	Light brown	1.49	17	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000
Type2 -v3	Pink	1.25	18	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000
Type2 -v4	Ivory	1.06	19	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000
Type2 -v5	Yellow	0.90	20	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000
Type2 -v6	Green	0.80	21	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000
Type2 -v7	Black	0.70	22	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000
Type2 -v8	Light blue	0.63	23	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000
Type2 -v9	Purple	0.55	24	200, 225, 250, 275, 300, 325, 350	200, 300, 400, 600, 800, 1000

- Kitazato OPU Reduced Needle, model number Type 3

Model	Needle Gauge	Needle O.D. (mm)	Narrow Tip Gauge	Narrow Tip O.D. (mm)	Needle Length (mm)	Color of Hub	Length of Reduced Needle (mm)	Connection Tube Length (mm)
Type3 -v1	18	1.25	21	0.80	200, 225, 250, 275, 300, 325, 350	Green	40-60	800
Type3 -v2	18	1.25	22	0.70	200, 225, 250, 275, 300, 325, 350	Black	40-60	800
Type3 -v3	18	1.20	23	0.63	200, 225, 250, 275, 300, 325, 350	Light blue	40-60	800

are intended to obtain oocytes from ovarian follicles.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)
AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert R. Lerner

Acting Director for Benjamin R. Fisher, Ph.D.

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112462