

510(k) Summary

For

Kitazato IUI Catheter – K131491

1. Submission Sponsor

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2. Submission Correspondent

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SEP 11 2013

3. Date Prepared

30 August 2013

4. Device Identification

Trade/Proprietary Name: Kitazato IUI Catheter
Common/Usual Name: Intrauterine Insemination (IUI) Catheter
Classification Name: Assisted Reproduction Catheter
Classification Regulation: 884.6110
Product Code: MQF
Device Class: II
Classification Panel: Obstetrics/Gynecology

5. Predicate Devices

Irvine Scientific Sales Co., Inc. – Wallace SIS/AI Catheter – K061679

6. Indication for Use

Kitazato IUI Catheter consist 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, 18cm, model number Type 3-v2

Kitazato IUI Catheter is used for the introduction of washed spermatozoa into the uterine cavity through the cervix.

7. Device Description

Kitazato IUI Catheter with Outer Stiffener Type with Stylet Cannula and without Stylet Cannula are recommended for uterine cervix with an anatomical curve because the catheter shaft can be easily manipulated. The Kitazato IUI Catheter is composed of an 18 cm catheter shaft 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, and a movable stopper to aid in delivery of the device to the targeted depth.

The catheter is composed of a polyvinyl chloride shaft and an ABS connector. The Stylet Cannula of the Type 3-v1 version of the device is composed of a stainless steel cannula (SUS304) and an ABS syringe connector. The Stylet Cannula 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. The spermatozoa can be introduced into the uterine cavity by the syringe that is connected to the stylet cannula with no need to remove the stylet cannula from the IUI Catheter. The syringe connector on both the catheter and stylet cannula has a 6% taper that is compatible with 6% taper connection syringe (note: syringe is not included with the catheter).

Model	Product Code Name	Catheter Body	Center Core Material	Catheter Length	Outer Diameter	Depth mark	Stopper	Stylet Cannula
Type3 -v1	Catheter with Outer Stiffener Type with Stylet Cannula	Polyvinyl chloride	None	18cm	2.00mm / 6Fr	Yes	Yes	Yes
Type3 -v2	Catheter with Outer Stiffener Type without Stylet Cannula	Polyvinyl chloride	None	18cm	2.00mm / 6Fr	Yes	Yes	No

Table 5A Comparison of Characteristics – Kitazato IUI Catheter with Outer Stiffener with Stylet Cannula, Type 3-v1

Manufacturer	KITAZATO Medical Co., Ltd.	Irvine Scientific Sales Co., Inc.	
Trade Name	Kitazato IUI Catheter with Outer Stiffener without Stylet Cannula	Wallace Artificial Insemination Catheter	Kitazato IUI Catheter Comparison to Predicate
510(k) Number	K131491	K061679	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 with Outer Stiffener with Stylet Cannula, 18 cm, model number Type 3-v1 is used for the introduction of washed spermatozoa into the uterine cavity through the cervix.	The Wallace SIS/AI Catheter is intended to be used in artificial insemination procedures intended for insertion of the catheter and introduction of washed spermatozoa into the uterine cavity. The Wallace SIS/AI Catheter is also intended to be used in Saline Infusion Sonography (SIS), also known as Saline Infusion Sonohysterography (SIS) and Saline Ultrasound Infusion procedures in the detection of abnormalities within uterine cavities.	Similar; both devices are indicated for delivery of washed spermatozoa to the uterine cavity. The predicate device is also indicated for Saline Infusion Sonography (SIS) which is not an indication for the Kitazato IUI Catheter. The Kitazato IUI Catheter is not intended to be used in SIS and Saline Ultrasound Infusion procedures, so there is no additional safety or efficacy concerns.
Overall Design	The Type 3-v1 device consists of an 18 cm catheter with a non-movable outer stiffening component to provide added rigidity. The catheter can be used with an additional included stylet catheter that provides further rigidity if needed. The catheter has a smooth distal tip with two side holes. The device includes depth markings and a movable depth stopper to aid in assessing depth of deployment into the uterus. The catheter is packaged in a single barrier sterilization pouch. A syringe is not included in the products.	The Wallace SIS/AI device consists of an 18 cm catheter with a movable outer stiffening component to provide added rigidity. The catheter has a smooth distal tip with two side holes. The device includes depth markings to aid in assessing depth of deployment into the uterus. The catheter is packaged in a single barrier sterilization pouch. A syringe is not included in the products.	The predicate device includes a movable outer stiffening component or what they refer to as the Outer Sheath; this is slid over the more flexible inner catheter. This has the same function as the Outer Stiffener on the Kitazato IUI Catheter. The overall design of the subject and predicate devices are similar, so there is no additional safety or efficacy concerns.
Sterile	Radiation	Ethylene Oxide (EO)	The predicate device is sterilized utilizing EO and the subject device with Radiation. The Kitazato IUI

Manufacturer	KITAZATO Medical Co., Ltd.	Irvine Scientific Sales Co., Inc.	
Trade Name	Kitazato IUI Catheter with Outer Stiffener without Stylet Cannula	Wallace Artificial Insemination Catheter	Kitazato IUI Catheter Comparison to Predicate
			Catheter is sterilized using a validated method for Radiation that does not introduce any additional safety or efficacy concerns.
Single-Use	Yes	Yes	Same
French Size	O.D. of Inner Catheter is 2 mm (6 Fr) (the Inner Catheter extends 4.5 cm beyond the Outer Stiffener) O.D. of Outer Stiffener is 2.5 mm (7.5 Fr)	Inner Catheter 16 gauge (1.29 mm) (the Inner Catheter extends 5 cm beyond the Outer Sheath)	Similar; the predicate device inner catheter shaft has similar diameters with the predicate device being slightly smaller. It is unclear what the outer diameter of the Wallace product is and there is no information on the company website. Based on the size of the inner catheter, the outer catheter may be approximately 1.8 to 2 mm which is comparable to the Kitazato IUI Catheter. There is no additional safety or efficacy concerns.
Length	18 cm	18 cm	Same
Depth Marks	Centimeter marks are located at 5, 6, 7, 8 cm from tip on the outer stiffer	1 cm graduations on Outer Catheter	Similar; the predicate device has graduations along the length of the catheter. The Kitazato product has markings included in the range of the predicate device for the area of application. This does not add any safety or efficacy concerns.
Tip	Closed and smoothly rounded; two side holes end type	Closed and smoothly rounded; two side holes end type	Same
Stylet	Yes	No	The additional stylet can be used to add further rigidity for the catheter to assist if the uterine cervix is curved. This does not impact the use of the device and adds no safety or efficacy concerns as the functionality of the stylet is commonly used with other catheters to provide additional rigidity.

Manufacturer	KITAZATO Medical Co., Ltd.	Irvine Scientific Sales Co., Inc.	
Trade Name	Kitazato IUI Catheter with Outer Stiffener without Stylet Cannula	Wallace Artificial Insemination Catheter	Kitazato IUI Catheter Comparison to Predicate
Movable Depth Stopper	Yes	No	The movable depth stopper is used as a reference point; the physician measures the length of uterus prior to insertion of the catheter and utilizes the stopper as a guide. This does not impact the use of the device and adds no safety or efficacy concerns.

Table 5B Comparison of Characteristics – Kitazato IUI Catheter with Outer Stiffener without Stylet Cannula, Type 3-v2

Manufacturer	KITAZATO Medical Co., Ltd.	Irvine Scientific Sales Co., Inc.	
Trade Name	Kitazato IUI Catheter with Outer Stiffener without Stylet Cannula	Wallace Artificial Insemination Catheter	Kitazato IUI Catheter Comparison to Predicate
510(k) Number	K131491	K061679	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 with Outer Stiffener without Stylet Cannula, 18 cm, model number Type 3-v2 is used for the introduction of washed spermatozoa into the uterine cavity through the cervix.	The Wallace SIS/AI Catheter is intended to be used in artificial insemination procedures intended for insertion of the catheter and introduction of washed spermatozoa into the uterine cavity. The Wallace SIS/AI Catheter is also intended to be used in Saline Infusion Sonography (SIS), also known as Saline Infusion Sonohysterography (SIS) and Saline Ultrasound Infusion procedures in the detection abnormalities within uterine cavities.	Similar; both devices are indicated for delivery of washed spermatozoa to the uterine cavity. The predicate device is also indicated for Saline Infusion Sonography (SIS) which is not an indication for the Kitazato IUI Catheter. The Kitazato IUI Catheter is not intended to be used in SIS and Saline Ultrasound Infusion procedures, so there is no additional safety or efficacy concerns.
Overall Design	The Type 3-v2 device consists of an 18 cm catheter with a non-movable outer stiffening component to provide added rigidity. The catheter has a smooth distal tip with two side holes. The device	The Wallace SIS/AI device consists of an 18 cm catheter with a movable outer stiffening component to provide added rigidity. The catheter has a smooth distal tip with two side holes. The	The predicate device includes a movable outer stiffening component or what they refer to as the Outer Sheath; this is slid over the more flexible inner catheter. This has the same

Manufacturer	KITAZATO Medical Co., Ltd.	Irvine Scientific Sales Co., Inc.	
Trade Name	Kitazato IUI Catheter with Outer Stiffener without Stylet Cannula	Wallace Artificial Insemination Catheter	Kitazato IUI Catheter Comparison to Predicate
	includes depth markings and a movable depth stopper to aid in assessing depth of deployment into the uterus. The catheter is packaged in a single barrier sterilization pouch. A syringe is not included in the products.	device includes depth markings to aid in assessing depth of deployment into the uterus. The catheter is packaged in a single barrier sterilization pouch. A syringe is not included in the products.	function as the Outer Stiffener on the Kitazato IUI Catheter. The overall design of the subject and predicate devices are similar, so there is no additional safety or efficacy concerns.
Sterile	Radiation	Ethylene Oxide (EO)	The predicate device is sterilized utilizing EO and the subject device with Radiation. The Kitazato IUI Catheter is sterilized using a validated method for Radiation that does not introduce any additional safety or efficacy concerns.
Single-Use	Yes	Yes	Same
French Size	O.D. of Inner Catheter is 2 mm (6 Fr) (the Inner Catheter extends 4.5 cm beyond the Outer Stiffener) O.D. of Outer Stiffener is 2.5 mm (7.5 Fr)	Inner Catheter 16 gauge (1.29 mm) (the Inner Catheter extends 5 cm beyond the Outer Sheath)	Similar; the predicate device inner catheter shaft has similar diameters with the predicate device being slightly smaller. It is unclear what the outer diameter of the Wallace product is and there is no information on the company website. Based on the size of the inner catheter, the outer catheter may be approximately 1.8 to 2 mm which is comparable to the Kitazato IUI Catheter. There is no additional safety or efficacy concerns.
Length	18 cm	18 cm	Same
Depth Marks	Centimeter marks are located at 5, 6, 7, 8 cm from tip on the outer stiffer	1cm graduations on Outer Catheter	Similar; the predicate device has graduations along the length of the catheter. The Kitazato product has markings included in the range of the predicate device for the area of application. This does not add any safety or efficacy concerns.
Tip	Closed and smoothly rounded; two side holes end type	Closed and smoothly rounded; two side holes end type	Same

Manufacturer	KITAZATO Medical Co., Ltd.	Irvine Scientific Sales Co., Inc.	
Trade Name	Kitazato IUI Catheter with Outer Stiffener without Stylet Cannula	Wallace Artificial Insemination Catheter	Kitazato IUI Catheter Comparison to Predicate
Stylet	No	No	Same
Movable Depth Stopper	Yes	No	The movable depth stopper is used as a reference point; the physician measures the length of uterus prior to insertion of the catheter and utilizes the stopper as a guide. This does not impact the use of the device and adds no safety or efficacy concerns.

8. Technological Characteristics

The indication for use and technology of the Kitazato IUI Catheter is substantially equivalent to the identified predicate devices.

9. Non-Clinical Testing

The catheter mechanical tensile testing, dimension testing, endotoxin testing, sterility testing and Human Sperm Survival Assay results support that all the specifications have met the acceptance criteria for the device.

- Mechanical Tensile Testing: Tensile strength passed the established specification
- 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
- Biocompatibility Testing: Passed all testing for cytotoxicity, intracutaneous reactivity, and sensitization
- Phthalates (DEHP) Release Testing: Passed according to specifications
- Human Sperm Survival Assay: $\geq 70\%$ motility at 24 hours
- Shelf Life Testing: Established three (3) years

The Kitazato IUI Catheter passed all testing and supports the claims of substantial equivalence and safe operation.

The Kitazato IUI Catheter complies with the applicable voluntary standards for biocompatibility and sterilization. The device passed all the testing in accordance with national and international standards.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate

devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The substantial equivalence of the device is supported by the non-clinical testing. The validation testing of the device biocompatibility and HSSA testing was found to be acceptable and supports the claims of substantial equivalence.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that any differences between the Kitazato IUI Catheter and the predicate device do not raise any questions regarding its safety and effectiveness. The Kitazato IUI Catheter, as designed and manufactured, is substantially equivalent to the referenced predicate devices.



September 11, 2013

KITAZATO Medical Co., Ltd.
% Richard A. Vincins, CBA, CQA, RAC
Vice President, QA
Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701

Re: K131491

Trade/Device Name: 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

Regulation Number: 21 CFR§ 884.6110
Regulation Name: Assisted reproduction catheters
Regulatory Class: II
Product Code: MQF
Dated: July 12, 2013
Received: July 15, 2013

Dear Richard A. Vincins, CBA, CQA, RAC,

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 P. Lerner -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

Indications for Use

510(k) Number (if known): K131491

Device Name: Kitazato IUI Catheter

Indications for Use:

Kitazato IUI Catheter consist 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.

Prescription Use (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 Center for Devices and Radiological Health (CDRH)

Herbert P. Lerner -S