September 26, 2019

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

Re: K190199
Trade/Device Name: SepaSperm Washing Solution, SepaSperm Solution
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: August 26, 2019
Received: August 27, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For
Sharon M. Andrews
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190199

Device Name
SepaSperm Washing Solution, SepaSperm Solution

Indications for Use *(Describe)*
SepaSperm Washing Solution is used for preparation and washing of sperm for use in assisted reproduction procedures.
SepaSperm Washing Solution is not intended for use in intrauterine insemination procedures.
SepaSperm Solution is used for separation of motile sperm from seminal fluid for use in assisted reproduction procedures.

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 – K190199

1. Submitter Information

Applicant: Kitazato Corporation
Contact: Mr. Futoshi Inoue
President and Representative Director
Address: 81 Nakajima, Fuji-shi
Shizuoka 416-0907
Japan

2. Correspondent Information

Contact: Audrey Swearingen
Manager, Regulatory Affairs
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Email: lst.aus.projectmanagement@ul.com

3. Date prepared: September 23, 2019

4. Device Information

Device Name:	SepaSperm Washing Solution, SepaSperm Solution
Common Name:	Sperm processing media
Regulation Number:	21 CFR 884.6180
Regulation Name:	Reproductive media and supplements
Regulatory Class:	Class II
Product Code:	MQL (media, reproductive)

5. Predicate Device Information

Device Name:	Sydney IVF Sperm Medium, Sydney IVF Sperm Gradient Kit, Sydney IVF Spermient
510(k) Number:	K152782
Manufacturer:	William A. Cook Australia Pty Ltd.
Regulatory Class:	Class II
Product Code:	MQL (media, reproductive)

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

6. Device Description

SepaSperm is used for preparation and washing of sperm and for separation of motile sperm from semen in assisted reproductive techniques.

The device includes two types of solutions used for density-gradient centrifugation:

- SepaSperm Solution for sperm preparation and separation from semen, and
- SepaSperm Washing Solution for sperm washing and preparation

Both solutions are provided in two sizes (100mL and 50mL bottles). This product is single-use only and includes no accessories. The product is provided sterile-filtered into a container that is sterilized by gamma irradiation.

SepaSperm Solution is offered in four different densities, determined by the amount of silica present:

- SepaSperm Solution 100%
- Lower layer solution 80%
- Middle layer solution 60%
- Upper layer solution 40%

SepaSperm Solution is composed of silica particles diluted with modified human tubal fluid (m-HTF) medium, with dextran and polyvinylpyrrolidone added. The m-HTF medium is a HEPES-buffered solution which is suitable for use in ambient conditions. All SepaSperm Solutions are provided with and without gentamicin. SepaSperm Solution has a shelf-life of six or 12 months for media without or with gentamicin, respectively.

The SepaSperm Washing Solution consists of m-HTF medium supplemented with dextran and polyvinylpyrrolidone. It contains no silica. SepaSperm Washing Solution is used to wash the prepared sperm and suspend the final pellet. SepaSperm Washing Solutions are provided with and without gentamicin. SepaSperm Washing Solution has a shelf-life of six or 12 months for media without or with gentamicin, respectively.

7. Indications for Use

SepaSperm Washing Solution is used for preparation and washing of sperm for use in assisted reproduction procedures. SepaSperm Washing Solution is not intended for use in intrauterine insemination procedures.

SepaSperm Solution is used for separation of motile sperm from seminal fluid for use in assisted reproduction procedures.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below lists the comparison of the indications for use and technological characteristics of the subject and predicate device.

Table 1: Comparison of Characteristics

Manufacturer	**Kitazato Corporation**	**William A. Cook Australia Pty Ltd.**
Trade Name	**SepaSperm Solution and SepaSperm Washing Solution**	**Sydney IVF Spermient, Sydney IVF Sperm Gradient Kit, and Sydney IVF Sperm Medium**
510(k) Number	K190199	K152782

Indications for Use	SepaSperm Washing Solution is used for preparation and washing of sperm for use in assisted reproduction procedures. SepaSperm Washing Solution is not intended for use in intrauterine insemination procedures. SepaSperm Solution is used for separation of motile sperm from seminal fluid for use in assisted reproduction procedures.	Sydney IVF Sperm Gradient Kit and Sydney IVF Spermient are intended for use during in vitro fertilization procedures to separate motile sperm from seminal plasma. Sydney IVF Sperm Medium is intended for use during in vitro fertilization procedures to process sperm.
Materials of Sperm Separation Solution	Silica, HEPES buffered salt solution, D-glucose, water, dextran, polyvinylpyrrolidone; includes options with and without gentamicin.	Not known
Materials of Sperm Washing Component	Same as those of the SepaSperm Solution (above), except that it does not contain silica.	Not known
Volume	50mL, 100mL	Sydney IVF Sperm Medium: 20 mL, 50 mL, and 100 mL Sydney IVF Sperm Gradient Kit: 20 mL and 50 mL Sydney IVF Spermient: 200 mL and 100 mL
Solution density (% silica)	SepaSperm Solution: 40%, 60%, 80%, 100%	Sperm Gradient Kit: 40% and 80%; Sydney IVF Spermient: 100%
Osmolality	270-300 mOsm/kg	285-295 mOsm/kg
pH	7.2 - 7.6	Sydney IVF Sperm Medium: 7.5-7.8 Sydney IVF Sperm Gradient Kit /Sydney IVF Spermient: 7.3-7.5
Sperm Survival Assay (HSSA)	≥80% of control motility at 24h	Performed, specification not known
Endotoxin	≤0.25 EU/mL	<0.4 EU/mL
Sterility	Sterile filtration	Sterile filtration

Storage temperature	2 - 8°C	2 - 8°C
Shelf Life	6 months (without gentamicin); 1 year (with gentamicin)	20 weeks

The subject and predicate device have similar indications for use and have the same intended use (preparation, separation, and washing of sperm for use in assisted reproduction procedures). The subject and predicate device have similar technological characteristics as shown in the table above (e.g., design, gradient concentrations, osmolality, pH, sterilization method, etc.). The different technological characteristics of the subject device (e.g., formulation, shelf-life, endotoxin specifications, etc.) do not raise different types of safety and effectiveness questions.

9. Summary of Non-Clinical Performance Testing

The following studies have been performed to support substantial equivalence to the predicate devices. Results confirm that the design inputs and performance specifications for the device are met.

- Shelf Life Performance Testing (Time 0 and end of shelf-life):
  - Appearance
  - Specific gravity: 1.0600-1.1200
  - pH, per USP <791>: 7.2 - 7.6
  - Osmolality, per USP <785>: 270-300 mOsm/Kg
  - Endotoxin, per USP <85>: < 0.25 EU/mL
  - HSSA: ≥80% of control motility at 24h
  - Sterility, per USP <71>: No microbial growth
- Sterile filtration and Aseptic fill validation, per ISO 13408-1:2008(R2013) and ISO 13408-2:2003(R)2013)
- Transportation testing per ASTM D4169-16
- Bottle seal strength testing and containers performance testing per <USP 671>
- Sperm assessment for motility, morphology, viability, purity, and integrity before and after separation procedures to assess the effectiveness of the device when used in the three separation modes stated in device labeling.

10. Conclusion

The results of the performance testing described above demonstrate that the SepaSperm Washing Solution and SepaSperm Solution are as safe and effective as the predicate device and supports a determination of substantial equivalence.