August 25, 2020

Kitazato Corporation
% Michael A. Siano, MA, RAC
Regulatory Affairs Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, TX 78746

Re: K193522
Trade/Device Name: iMedium Single Step; iMedium Single Step with HSA; iMedium Single Step with rHA
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: July 21, 2020
Received: July 23, 2020

Dear Michael A. Siano:

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,

Monica D. Garcia, Ph.D.
Acting 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)*
K193522

Device Name
iMedium Single Step; iMedium Single Step with HSA; iMedium Single Step with rHA

Indications for Use *(Describe)*
iMedium Single Step media are intended to be used as culture media for gametes and embryos from fertilization through day 5/6 of development. iMedium Single Step media are not intended for embryo transfer 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

K193522 – iMedium Single Step Media

1. Submission Sponsor

Applicant:	Kitazato Corporation
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	President and Representative Director
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2. Correspondent Information

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	Regulatory Affairs Consultant
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3. Date Prepared: August 24, 2020

4. Device Identification

Device Name:	iMedium Single Step; iMedium Single Step with HSA; iMedium Single Step with rHA
Common Name:	Culture Medium
Regulation Number:	21 CFR 884.6180
Regulation Name:	Reproductive media and supplements
Product Code:	MQL (Media, Reproductive)
Regulatory Class:	Class II

5. Predicate Device(s)

Device Name:	Continuous Single Culture®-NX (CSCM-NX)
510(k) Number:	K170681

Manufacturer: Irvine Scientific Sales Co., Inc.

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

6. Device Description

The Kitazato iMedium Single Step media are culture media used in assisted reproductive procedures. The iMedium Single Step media are designed for development of the embryo from fertilization through day 5/6 until the embryo transfer, in a continuous and uninterrupted culture system without the need to change media.

The iMedium Single Step media are provided in three variants: without protein (Model: IM-S), with human serum albumin (HSA; Model: IM-SS), and with recombinant human albumin (rHA; Model: IM-SC). All variants contain gentamicin, an antibiotic agent that suppresses bacterial growth. Each iMedium Single Step solution is offered in three volumes (10mL, 50mL and 100mL).

Each iMedium Single Step solution is a colorless, odorless and clear fluid. The product is single-use only, provided aseptically-filtered in a container sterilized by gamma irradiation.

7. Indications for Use Statement

iMedium Single Step media are intended to be used as culture media for gametes and embryos from fertilization through day 5/6 of development. iMedium Single Step media are not intended for embryo transfer procedures.

8. Substantial Equivalence Discussion

A detailed comparison of the intended use and technological features of the subject and predicate device are described in the tables below:

Table 1: Comparison of Intended use and Technological Characteristics

Attribute	**K193522** **Subject Device:** **iMedium Single Step Media**	**K170681** **Predicate Device** **Continuous Single Culture-NX**	**Comparison**
Manufacturer	Kitazato Corporation	Irvine Scientific Sales Co., Inc.	Different
Product Code	MQL	MQL	Same
Indications for Use	iMedium Single Step media are intended to be used as culture media for gametes and embryos from fertilization through day 5/6 of development. iMedium Single Step media are not intended for embryo transfer procedures.	The Continuous Single Culture®-NX (CSCM-NX) is intended for use as a culture medium for human gametes and embryos from fertilization through day 5/6 of development in vitro.	Different

Rx/OTC	Rx	Rx	Same
Ingredients	Sodium Chloride, Potassium chloride, Potassium dihydrogen phosphate, Magnesium sulphate heptahydrate, Sodium DL-lactate solution, Sodium pyruvate, D-glucose, Sodium hydrogen carbonate, Calcium chloride dihydrate, Alanyl-glutamine, Polyvinyl alcohol (30,000), Gentamicin, Non-essential amino acid, Essential amino acid, r-Insulin, HSA (in IM-SS models), rHA (in IM-SC models)	Salts, energy substrates, buffer, nutrients supplements, amino acids, antibiotic	Different
Volumes	10, 50, 100 mL	20, 60 mL	Different
pH	7.2–7.6	7.25–7.54	Similar
Endotoxin	≤ 0.25 EU/mL	≤ 0.25 EU/mL	Same
1-Cell Mouse Embryo Assay (MEA)	≥ 80 % embryos developed to expanded blastocyst at 96 hours	≥ 80 % developed to the blastocyst stage at 96 hours	Same
Sterility	No growth	No growth	Same
Storage Condition	2 – 8 °C	2 – 8 °C	Same
Shelf Life	4 months	4 months	Same
Sterilization	Aseptic filtration	Aseptic filtration	Same
Single-Use	Yes	Yes	Same

The subject and predicate device have similar indications for use statements and have the same intended use – to culture gametes and embryos through day 5/6 of development prior to use in assisted reproductive technology procedures. The subject and predicate device have different technological characteristics, including differences in formulation, pH, specifications, and package volumes. These differences do not raise different questions of safety and effectiveness as compared to the predicate device.

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of iMedium Single Step media and to show substantial equivalence to the predicate device, Kitazato completed the following non-clinical tests. Results confirm that the performance specifications for the iMedium Single Step media are met.

The device passed all testing in accordance with internal requirements, national standards, and international standards shown below:

- Appearance
- pH per USP <791>
- Osmolarity testing using freezing point depression method
- Endotoxin testing per USP <85> (*Bacterial Endotoxins Test*)
- 1-Cell MEA
- Sterility testing per USP <71> (*Sterility Tests*)

Shelf-life performance testing was conducted at time 0 and at the end of shelf-life (4 months real-time aged samples) to ensure the product specifications listed above were met. Real-time aged samples also underwent transportation testing per ASTM D4169-16 (*Standard Practice for Performance Testing of Shipping Containers and Systems*) and passed all testing.

Sterilization validation was tested per ISO 13408-1: 2008 / A1:2013 (*Aseptic processing of health care products - Part 1: General requirements*) and ISO 13408-2: 2018 (*Aseptic processing of health care products - Part 2: Sterilizing filtration*). The samples passed all testing.

10. Conclusion

The results of the performance testing described above demonstrate that iMedium Single Step media are as safe and effective as the predicate device and supports a determination of substantial equivalence.