October 23, 2020

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

Re: K200249
Trade/Device Name: Sequential Culture Media (Fertilization Medium [without HSA/rHA, with HSA, with rHA], Cleavage Medium [without HSA/rHA, with HSA, with rHA], and Blastocyst Medium [without HSA/rHA, with HSA, with rHA])
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: September 22, 2020
Received: September 24, 2020

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,

Monica D. Garcia, Ph.D.
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)*
K200249

Device Name
Sequential Culture Media (Fertilization Medium [without HSA/rHA, with HSA, with rHA], Cleavage Medium [without HSA/rHA, with HSA, with rHA], and Blastocyst Medium [without HSA/rHA, with HSA, with rHA])

Indications for Use *(Describe)*
Sequential Culture Media consists of Fertilization Medium, Cleavage Medium, and Blastocyst Medium that are intended to be used sequentially from fertilization to the blastocyst stage of development. The intended uses of the Fertilization Medium, Cleavage Medium, and Blastocyst Medium are as follows:

Fertilization medium is intended for use during in vitro fertilization (IVF) and intracytoplasmic sperm insertion (ICSI) procedures and culture to the two pronuclei (zygote) stage of development.

Cleavage Medium is intended for culture of embryos from the two pronuclei (zygote) stage to the 8-cell stage of development. Cleavage Medium is not intended for transferring embryos to the uterine cavity

Blastocyst Medium is intended for culture from the 8-cell stage to the blastocyst stage of development. Blastocyst Medium is not intended for transferring embryos to the uterine cavity

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

K200249 - Sequential Culture Media (Fertilization Medium [without HSA/rHA, with HSA, with rHA], Cleavage Medium [without HSA/rHA, with HSA, with rHA], Blastocyst Medium [without HSA/rHA, with HSA, with rHA])

1. Submitter Information

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

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Email:	LST.AUS.ProjectManagement@ul.com

3. Date Prepared

October 23, 2020

4. Device Identification

Device Name:	Sequential Culture Media (Fertilization Medium [without HSA/rHA, with HSA, with rHA], Cleavage Medium [without HSA/rHA, with HSA, with rHA], Blastocyst Medium [without HSA/rHA, with HSA, with rHA])
Common Name:	Reproductive Culture Media
Regulation Number:	21 CFR 884.6180
Regulation Name:	Reproductive media and supplements
Product Code:	MQL (Media, Reproductive)

Class: Class II

5. Predicate Device

Device Name: Sydney IVF Fertilization Medium, Cleavage Medium, Blastocyst Medium

510(k) Number: K153290

Manufacturer: Cook Medical, Inc.

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

6. Device Description

Sequential Culture Media are intended for use sequentially from fertilization to late embryonic stages during assisted reproduction technology procedures for insemination and embryo culture.

The Sequential Culture Media is provided in three variants: Fertilization Medium, Cleavage Medium, and Blastocyst Medium. Each variant is provided with or without protein (human serum albumin (HSA) or recombinant HSA (rHA)). All variants contain gentamicin, an antibiotic agent that suppresses bacterial growth. Each Sequential Culture Media solution is offered in three volumes (10mL, 50mL and 100mL).

The following models are provided:

Model No.	Description
SK01-10	Sequential Culture Media Fertilization Medium 10mL
SK01-50	Sequential Culture Media Fertilization Medium 50mL
SK01-100	Sequential Culture Media Fertilization Medium 100mL
SK01S-10	Sequential Culture Media Fertilization Medium with HSA 10mL
SK01S-50	Sequential Culture Media Fertilization Medium with HSA 50mL
SK01S-100	Sequential Culture Media Fertilization Medium with HSA 100mL
SK01C-10	Sequential Culture Media Fertilization Medium with rHA 10mL
SK01C-50	Sequential Culture Media Fertilization Medium with rHA 50mL
SK01C-100	Sequential Culture Media Fertilization Medium with rHA 100mL
SK02-10	Sequential Culture Media Cleavage Medium 10mL
SK02-50	Sequential Culture Media Cleavage Medium 50mL
SK02-100	Sequential Culture Media Cleavage Medium 100mL
SK02S-10	Sequential Culture Media Cleavage Medium with HSA 10mL
SK02S-50	Sequential Culture Media Cleavage Medium with HSA 50mL
SK02S-100	Sequential Culture Media Cleavage Medium with HSA 100mL
SK02C-10	Sequential Culture Media Cleavage Medium with rHA 10mL
SK02C-50	Sequential Culture Media Cleavage Medium with rHA 50mL
SK02C-100	Sequential Culture Media Cleavage Medium with rHA 100mL
SK03-10	Sequential Culture Media Blastocyst Medium 10mL
SK03-50	Sequential Culture Media Blastocyst Medium 50mL
SK03-100	Sequential Culture Media Blastocyst Medium 100mL

SK03S-10	Sequential Culture Media Blastocyst Medium with HSA 10mL
SK03S-50	Sequential Culture Media Blastocyst Medium with HSA 50mL
SK03S-100	Sequential Culture Media Blastocyst Medium with HSA 100mL
SK03C-10	Sequential Culture Media Blastocyst Medium with rHA 10mL
SK03C-50	Sequential Culture Media Blastocyst Medium with rHA 50mL
SK03C-100	Sequential Culture Media Blastocyst Medium with rHA 100mL

The Sequential Culture Media solution is a colorless, odorless, clear fluid, provided sterile-filtered into a container pre-sterilized by gamma irradiation. The primary container of Sequential Culture Media 10mL is a sterile non-pyrogenic PETG vial, and the primary container of the Sequential Culture Media 50mL and 100mL is a square, non-pyrogenic PETG bottle. The containers are manufactured and provided sterile (with a SAL of 10^{-6}) by ThermoFisher Scientific, Inc. After sterile-filling, the top of the vial and bottle are sealed with tamper-evident shrink-wrap.

The complete device specifications are listed in Table 1 below.

7. Indication for Use Statement

Sequential Culture Media consists of Fertilization Medium, Cleavage Medium, and Blastocyst Medium that are intended to be used sequentially from fertilization to the blastocyst stage of development. The intended uses of the Fertilization Medium, Cleavage Medium, and Blastocyst Medium are as follows:

Fertilization medium is intended for use during in vitro fertilization (IVF) and intracytoplasmic sperm insertion (ICSI) procedures and culture to the two pronuclei (zygote) stage of development.

Cleavage Medium is intended for culture of embryos from the two pronuclei (zygote) stage to the 8-cell stage of development. Cleavage Medium is not intended for transferring embryos to the uterine cavity.

Blastocyst Medium is intended for culture from the 8-cell stage to the blastocyst stage of development. Blastocyst Medium is not intended for transferring embryos to the uterine cavity.

8. Substantial Equivalence Discussion

The following table compares the intended use and technological features of the subject and predicate device:

Table 1 – Comparison of Characteristics

Device Attribute	**K200249: Kitazato Sequential Culture Media**	**K153290: Cook Sydney IVF Media**	**Comparison**
Manufacturer	Kitazato	Cook Medical, Inc.	Different
Product Code	MQL	MQL	Same
Indications for Use	Sequential Culture Media consists of Fertilization	Sydney IVF Fertilization Medium is intended for use	Different

	Medium, Cleavage Medium, and Blastocyst Medium that are intended to be used sequentially from fertilization to the blastocyst stage of development. The intended uses of the Fertilization Medium, Cleavage Medium, and Blastocyst Medium are as follows: Fertilization medium is intended for use during in vitro fertilization (IVF) and intracytoplasmic sperm insertion (ICSI) procedures and culture to the two pronuclei (zygote) stage of development. Cleavage Medium is intended for culture of embryos from the two pronuclei (zygote) stage to the 8-cell stage of development. Cleavage Medium is not intended for transferring embryos to the uterine cavity. Blastocyst Medium is intended for culture from the 8-cell stage to the blastocyst stage of development. Blastocyst Medium is not intended for transferring embryos to the uterine cavity.	during in vitro procedures for insemination and incubation of oocytes. Sydney IVF Cleavage Medium is intended for use during in vitro fertilization procedures for culture and transfer of cleavage stage embryos. Sydney IVF Blastocyst Medium is intended for use during in vitro fertilization procedures for extended culture and transfer of embryos.	
Rx/OTC	Rx	Rx	Same
Volumes	10, 50, 100 mL	20, 50, 100 mL	Different
Ingredients	Salts, Energy substrates, Buffer, anti-oxidant, nutrient supplements, Amino acids, Antibiotic, protein	Salts, Energy substrates, Buffer, anti-oxidant, nutrient supplements, Amino acids, Antibiotic, protein	Different

pH	7.2-7.6	7.5-7.8	Different
Osmolality	270-290 mOsm/L	- Fertilization Medium: 285-295mOsm/kg -Cleavage Medium: 285-295mOsm/kg - Blastocyst Medium: 280-290mOsm/kg	Different
Endotoxin	≤ 0.25 EU/mL	< 0.4 EU/mL	Different
MEA	≥ 80% of one cell mouse embryos developed to expanded blastocyst at 96 hours	≥ 80% expanded blastocyst at 72 hours	Different
Sterilization method	Sterile-filtered	Sterile-filtered	Same
Sterility	No growth	No growth	Same
Single-Use	Yes	Yes	Same
Storage Condition	2 – 8 °C	2 – 8 °C	Same
Shelf Life	4 months	20 weeks	Different

The subject and predicate device have similar indications for use statements and have the same intended use - to support fertilization and embryo development in assisted reproductive technology procedures. The subject and predicate device have different technological characteristics, including differences in formulation, pH, osmolality, endotoxin, storage conditions, MEA, and shelf-life. These differences do not raise different questions of safety and effectiveness as compared to the predicate device.

9. Summary of Non-Clinical Performance Testing

To demonstrate safety and effectiveness of Sequential Culture Media and to show substantial equivalence to the predicate device, Kitazato Corporation completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the Sequential Culture Media are met.

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

- Performance Testing:
  - Appearance: Clear, particulate-free
  - pH, per *USP <791>*: 7.2 - 7.6
  - Osmolarity, using freezing depression method: 270-295 mOsm/L
  - Endotoxin, per *USP <85>*: ≤ 0.25 EU/mL
  - MEA: ≥ 80% of 1-cell mouse embryos developed to expanded blastocyst at 96 hours
  - Sterility, per *USP <71>*: No microbial growth

- Stability testing: real-time aged samples at baseline (Time 0) and 4 months for the performance specifications above
- Sterile filtration and aseptic fill validation, per *ISO 13408-1:2008/A1:2013* and *ISO 13408-2:2018*
- Container Seal testing, per *USP <671>:* ≤ 5.0% permeability and ≤ 1 sample exceeding 2.50% over the 14 days
- Transportation Testing per *ASTM D4169* – Package integrity and device performance maintained

10. Conclusions

The results of the performance testing described above demonstrate that the Sequential Culture Media are as safe and effective as the predicate device and supports a determination of substantial equivalence.