October 13, 2017

ORIGIO a/s
Tove Kjaer
Director, Corporate Regulatory Affairs
Knardrupvej 2
Malov, 2760 Denmark

Re: K172197
Trade/Device Name: SAGE 1-Step™ GM-CSF with HSA,
SAGE 1-Step™ GM-CSF with SPS
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: Class II
Product Code: MQL
Dated: July 24, 2017
Received: July 26, 2017

Dear Tove Kjaer:

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 contact the Division of Industry and Consumer Education (DICE) 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. 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 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 Industry and Consumer Education (DICE) 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,

Joyce M. Whang -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

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)*
K172197

Device Name
SAGE 1-Step™ GM-CSF with HSA
SAGE 1-Step™ GM-CSF with SPS

Indications for Use *(Describe)*
The product is intended for in vitro culture of human embryos following fertilization until Day 5/6 of development. The media can also be used for embryo transfer

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY
K172197

I. Submitter Information

Submitter:

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II. Date prepared:

Oct. 13 2017

III. Device Information

Device Name:	SAGE 1-Step™ GM-CSF with HSA SAGE 1-Step™ GM-CSF with SPS
Common name:	Embryo Culture Media
Classification name:	Reproductive media and supplements
Classification Number:	21 CFR 884.6180
Product Code:	MQL (Media, Reproductive)
Regulatory Class:	II

IV. Predicate Device

ORIGIO a/s - SAGE 1-Step™ with HSA and SAGE 1-Step™ with SPS (K133707)

These predicate devices have not been subject to any design-related recalls.

V. Indication for use

The product is intended for in vitro culture of human embryos following fertilization until Day 5/6 of development. The media can also be used for embryo transfer.

VI. Device Description

SAGE 1-Step™ GM-CSF with HSA and SAGE 1-Step™ GM-CSF with SPS are assisted reproduction embryo culture media products consisting of buffering agents, physiological salts, energy substrates, amino acids, antibiotics, protein supplements (HSA or SPS), and granulocyte-macrophage colony-stimulating factor (GM-CSF, 2 ng/ml).

These devices are aseptically filtered (sterility assurance level of 10^{-3}), and supplied in 3 ml glass vials. They are tested for pH, osmolality, embryotoxicity, endotoxin, sterility, and GM-CSF concentration and potency before lot release. These devices have a shelf-life of 16 weeks, and can be used for up to seven days after vial opening when stored at 2-8°C.

VII. Comparison of Intended Use and Technological Characteristics of Subject and Predicate Devices

Parameter	**Subject device-** SAGE 1-Step™ GM-CSF (with HAS or SPS) (K172197)	**Predicate Device-** SAGE 1-Step™ (with HAS or SPS) (K133707)	**Comparison**
Indications for Use	The product is intended for in vitro culture of human embryos following fertilization until Day 5/6 of development. The media can also be used for embryo transfer.	This product is intended for *in vitro* fertilization and culture of human gametes and embryos from fertilization until Day 5/6 of development. The medium can also be used for embryo transfer.	**Different-** The subject and predicate devices are both indicated for culturing embryos following fertilization until the blastocyst stage (Day 5/6) of development, and for use in embryo transfer procedures. The predicate is also indicated for use during fertilization, which is different than the subject device. This difference does not represent a new intended use, but rather a more limited use of the subject device.
Formulation	Buffering agents, physiological salts,	Buffering agents, physiological salts,	**Different –**Base formulations of the

	energy substrates, amino acids, antibiotics, protein supplements (HSA or SPS), and GM-CSF	energy substrates, amino acids, antibiotics, and proteins supplements (HSA or SPS)	subject and predicate devices are similar; however, the subject device also includes GM-CSF. This difference does not raise different questions of safety and effectiveness (e.g., biocompatibility, embryotoixity, etc.).
pH	7.2-7.4	7.2-7.4	**Same**
Osmolality	257-273	257-273	**Same**
MEA	1-Cell MEA: ≥80% blastocysts at 96h	1-Cell MEA: ≥80% blastocysts at 96h	**Same**
Endotoxin (EU/ml)	<0.15	<0.15	**Same**
Sterility	Aeptic Filteration SAL 10^{-3}, no growth	Aeptic Filteration SAL 10^{-3}, no growth	**Same**
Shelf-Life	16 weeks	26 weeks	**Different –** The shelf-life of the subject and predicate devices are different. This difference does not raise different questions of safety and effectiveness.

As noted in the table above, the devices have the same intended use and are technologically comparable. Differences in technological characteristics noted above do not raise different questions of safety or effectiveness.

VIII. Summary of Non-Clinical Performance Testing

The following studies have been performed to support substantial equivalence to the predicate devices:

- pH – 7.2-7.4
- Osmolality - 257-273 mOsm/kg
- Aseptic processing validation testing that meet the requirements in ISO 13408-2-2003

- Sterility testing per USP <71> - No microbial growth
- Endotoxin testing per USP <85> - <0.15 EU/ml (LAL)
- Mouse embryo assay (MEA) – 1-Cell MEA: ≥80% blastocysts at 96h

  One-cell mouse embryos were exposed to subject devices and cultured at 37°C in an atmosphere containing 5% CO_2. The percent of embryos developed to the blastocyst stage at 96 hours were assessed in comparison with the control group.
- GM-CSF concentration (by ELISA) – 80-120% recovery
- GM-CSF potency (TF-1 cell assay) – 80-125% potency
- Shelf-life testing (real-time) was conducted to ensure that the following product specifications are met at time zero and the end of shelf-life.
  - pH
  - Osmolality
  - 1-Cell MEA
  - Endotoxin
  - Sterility
  - GM-CSF concentration
  - GM-CSF potency

IX. Conclusion

The results of the performance testing conducted on the subject devices demonstrates that they are as safe and effective as the predicate devices and support substantial equivalence.