DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 4, 2017

CooperSurgical, Inc.
% Tove Kjær
Director Corporate Regulatory Affairs
Origio a/s
Knardrupvej 2
Måløv, 2760
Denmark

Re: K170560
Trade/Device Name: SAGE Vitrification Kit
SAGE Vitrification Warming Kit
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: February 23, 2017
Received: March 6, 2017

Dear Tove Kjær:

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 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 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,

Benjamin R. Fisher -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170560

Device Name
SAGE Vitrification Kit
SAGE Vitrification Warming Kit

Indications for Use *(Describe)*
SAGE Vitrification Kit: These products are intended for ultra-rapid freezing and containment of human blastocysts in assisted reproductive technology procedures. This kit is designed to be used in conjunction with the SAGE Vitrification Warming Kit (ART-8031) for optimal recovery of specimens.

SAGE Vitrification Warming Kit: These products are intended for the recovery of human blastocysts that have undergone ultra-rapid freezing and containment using SAGE Vitrification Kit (ART-8026) for assisted reproductive technology 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

510(k) Number: **K170560**

Submitted on behalf of

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Date prepared April 3, 2017

Device identification:

Trade name	SAGE Vitrification Kit SAGE Vitrification Warming Kit
Common name	Vitrification Kit and Vitrification Warming Kit
Classification number	21 CFR 884.6180, Reproductive Media and Supplements
Product code	MQL, Media, Reproductive
Regulatory class	Class II

Predicate device

SAGE In-Vitro Fertilization, Inc. - Vitrification Kit and Vitrification Warming Kit (K073522)

The predicate devices have not been subject to any design-related recall.

Device description:

SAGE Vitrification Kit:
This kit includes two solutions (Equilibration Solution and Vitrification Solution). Both solutions in the kit consist of a MOPS- buffered media containing non-essential and essential amino acids, gentamicin sulfate, and human serum albumin. These solutions also contain the cryoprotectants ethylene glycol, dimethyl sulfoxide (DMSO) and sucrose as described below:

Equilibration Solution: 7.5% (v/v) each of DMSO and ethylene glycol.

Vitrification Solution: 15% (v/v) each of DMSO and ethylene glycol, and 0.6 M sucrose

SAGE Vitrification Warming Kit:
This kit includes three solutions (1.0 M Sucrose Warming Solution, 0.5 M Warming Solution, and MOPS Solution). All solutions in the kit consist of a MOPS- buffered media containing non-essential and essential amino acids, gentamicin sulfate, and human serum albumin. These solutions contain the cryoprotectant sucrose at the level described in their names (i.e., 1.0 M, 0.5 M, or no sucrose).

Solutions in the SAGE Vitrification Kit and SAGE Vitrification Warming Kit are aseptically-filtered and are provided to users in 2 ml polypropylene vials. The solutions in these kits are considered single-use devices.

Use environment:
The media are used in clinics working with assisted reproductive technology procedures

Device function:
The SAGE Vitrification Kit is designed to facilitate dehydration of blastocysts before vitrification via rapid cooling in liquid nitrogen. Dehydration of the blastocysts is achieved by the step-wise use of increasing concentration of cryoprotectants in the SAGE Vitrification Kit, which results in water being withdrawn from the cell. The cryoprotectants also protect the blastocysts by reducing the potential for ice crystal formation during the vitrification process.

The SAGE Vitrification Warming Kit is designed to facilitate the re-hydration (warming) of blastocysts after the cells have been vitrified. In the warming process, sucrose in the media manages the inflow of water into blastocysts as concentrations of DMSO and ethylene glycol are reduced during the rehydration process.

Modification of existing devices:
This submission covers two modifications to the currently marketed predicate device cleared under K073522. The first modification was a change in the primary packaging from a Type I borosilicate vial with a siliconized rubber stopper and an aluminum seal to polypropylene copolymer vials. The second modification was an extension of the shelf-life from 26 weeks to 52 weeks.

Indication for Use
SAGE Vitrification Kit: These products are intended for ultra-rapid freezing and containment of human blastocysts in assisted reproductive technology procedures. This kit is designed to be used in conjunction with the SAGE Vitrification Warming Kit (ART-8031) for optimal recovery of specimens.

SAGE Vitrification Warming Kit: These products are intended for the recovery of human blastocysts that have undergone ultra-rapid freezing and containment using SAGE Vitrification Kit (ART-8026) for assisted reproductive technology procedures.

Comparison of Intended Use and Technological Characteristics

Parameter	K170560 Subject Device	K073522 Predicate Device	Comments
Indication for use	SAGE Vitrification Kit: These products are intended for ultra-rapid freezing and containment of human blastocysts in assisted reproductive technology procedures. This kit is designed to be used in conjunction with the SAGE Vitrification Warming Kit (ART-8031) for optimal recovery of specimens.	Vitrification Kit: These products are intended for ultra-rapid freezing and containment of human blastocysts for Assisted Reproductive Technology (A.R.T.) procedures. This kit is designed for use with Sage IVF's Vitrification Warming Kit (Ref # ART-8030) for optimal recovery of specimens.	Similar: The indications for use for the subject device are similar to the predicate device; however, they are not identical. Although minor differences in text exist, the underlying use in vitrifying and warming human blastocyst stage embryos is the same. Therefore, the subject and predicate devices have the same Intended Use.
	SAGE Vitrification Warming Kit: These products are intended for the recovery of human blastocysts that have undergone ultra-rapid freezing and containment using SAGE Vitrification Kit (ART-8026) for assisted reproductive technology procedures.	Vitrification Warming Kit: These products are intended for the recovery of human blastocysts that have undergone ultra-rapid freezing and containment using Sage IVF's Vitrification Kit (Ref # ART-8025) for Assisted Reproductive Technology (A.R.T.) procedures.	
Formulation	Ethylene Glycol DMSO Sucrose Human Serum Albumin Gentamicin MOPS-Buffered Amino Acids Normal Salts	Ethylene Glycol DMSO Sucrose Human Serum Albumin Gentamicin MOPS-Buffered Amino Acids Normal Salts	Same

Cryoprotectants in Vitrification Solutions	Equil. Sol. 7.5% DMSO/7.5% Ethylene Glycol Vit. Sol.15% DMSO/15% Ethylene Glycol/0.6M Sucrose	Equil. Sol. 7.5% DMSO/7.5% Ethylene Glycol Vit. Sol.15% DMSO/15% Ethylene Glycol/0.6M Sucrose	Same
Cryoprotectants in Warming Solutions	0-1.0 M Sucrose as identified by solution name 1.0 M Sucrose Sol. 0.5 M Sucrose Sol MOPS Sol. (no sucrose)	0-1.0 M Sucrose as identified by solution name 1.0 M Sucrose Sol. 0.5 M Sucrose Sol MOPS Sol. (no sucrose)	Same
MEA	≥80% blastocysts at 96h	≥80% blastocysts at 96h	Same
Endotoxin	<0.5EU/ml	<0.5EU/ml	Same
Osmolality (mOsm/Kg)	Equil. Sol. 2331-2849 Vit. Sol. 5603-6849 1.0 M Sucrose 1255-1535 0.5M Sucrose 745-911 MOPS 257-273	Equil. Sol. 2331-2849 Vit. Sol. 5603-6849 1.0 M Sucrose 1235-1535 0.5M Sucrose 745-911 MOPS 257-273	Similar –The specification for the subject 1.0 M Sucrose Solution is tighter than that of the prior cleared device. This minor difference does not raise different questions of safety or effectiveness (S&E).
pH	7.2-7.4	7.2-7.4	Same
Sterilization	Membrane filtration SAL 10^{-3} USP<71>	Membrane filtration SAL 10^{-3} USP<71>	Same
Single-Use	Single	Single	Same
Shelf-Life	52 Weeks	26 Weeks	Different – The shelf-life is longer in the subject device. Differences in shelf-life do not raise different questions of S&E.
Device Packaging	Polypropylene vials Gamma irradiated, 10^{-6}	Glass vial with a siliconized rubber stopper and aluminum seal. Steam sterilized, 10^{-6}	Different – Packaging has moved from steam-sterilized glass vials to gamma irradiated polypropylene vials. Differences in vial materials/sterilization methods do not raise different questions of S&E.

As noted in the table above, the devices have the same intended use and are technologically comparable. Differences in technological characteristics noted included a minor difference in the osmolality specification for one media, and differences in shelf-life length and device packaging. As noted in the table, these differences do not raise different questions of safety or effectiveness.

Sterilization
Solutions in these kits are aseptically filtered, and have a Sterility Assurance Level of 10^{-3}. Validation of the media sterilization process was not re-assessed in the current submission as the aseptic filtration process is the same as that provided in the predicate submission (K073522).

Stability and Shelf-life:
Real-time shelf-life testing was conducted to demonstrate a 52-week shelf-life for the SAGE Vitrification Kit and SAGE Vitrification Warming Kit.

Stability testing included assessments of pH, osmolality, endotoxin, MEA, and sterility. All devices tested met the acceptance criteria described in the comparison table above.

Transportation testing:
Transportation testing on the SAGE Vitrification Kit and SAGE Vitrification Warming Kit was conducted in accordance with ASTM D4169-08, Standard Practice for Performance Testing of Shipping Containers and Systems. Samples tested did not show any signs of negative effects from simulated handling/transportation and met vial leakage acceptance specifications.

Conclusion:
The results of the performance testing conducted on the subject device demonstrate that it is as safe and effective as the predicate device and supports substantial equivalence.