



Food and Drug Administration
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December 21, 2015

Vitrolife Sweden AB
% Brett Sonet Glazar
Vitrolife, Inc.
Embryologist & MEA Laboratory Manager
3601 South Inca Street
Englewood, CO 80110

Re: K150950
Trade/Device Name: Freezekit™ Cleave, Thawkit™ Cleave
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: Class II
Product Code: MQL
Dated: November 9, 2015
Received: November 10, 2015

Dear Brett Sonet Glazar,

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 yours,


Herbert P. Lerner -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

Indications for Use

510(k) Number (if known)

K150950

Device Name

FreezeKit™ Cleave and ThawKit™ Cleave

Indications for Use (Describe)

FreezeKit™ Cleave is intended for freezing of pronuclear (2PN) and cleavage-stage embryos.

ThawKit™ Cleave is intended for thawing of frozen pronuclear (2PN) and cleavage-stage embryos.

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

Submitted by: Vitrolife Sweden AB
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Date Prepared: November 21, 2014

Trade Name: FreezeKit™ Cleave and ThawKit™ Cleave

Common Name: Assisted Reproduction Media for cryopreservation

Classification Name: Reproductive Media and Supplements
(21 C.F.R. § 884.6180)

Predicate Devices: Cook IVF Cryopreservation Kit and Cook IVF Thawing Kit (K011157)

Devices Description:

FreezeKit™ Cleave and ThawKit™ Cleave are devices used for freezing of pronuclear (2PN) and cleavage-stage embryos, and thawing of frozen pronuclear (2PN) and cleavage-stage embryos during *in vitro* fertilization (IVF) procedures.

The proposed devices are two separate kits, containing two and three solutions respectively. The two kits are marketed separately, yet are recommended to be used together to perform freezing and thawing. All solutions in both kits contain MOPS buffered solution, gentamicin as an antibacterial agent, human serum albumin and hyaluronan. The

cryoprotectants 1,2 - propanediol and sucrose are included in the freezing solution, and only sucrose is included as a cryoprotectant in the thawing solutions.

Indications for Use:

FreezeKit™ Cleave is intended for freezing of pronuclear (2PN) and cleavage stage embryos.

ThawKit™ Cleave is intended for thawing of frozen pronuclear (2PN) and cleavage-stage embryos.

The subject device indications for use are slightly different from the predicate device, which is indicated more generally for cryopreservation and thawing of zygotes and embryos. However, this difference does not alter the intended use of the subject device from that of the predicate. The intended use of the subject and predicate devices are comparable.

Technological Characteristics Comparison

The formulation of the subject devices are similar to that of the predicates. The compositions of the proposed devices and predicate devices contain antibiotics (gentamicin) and human serum albumin (HSA), as well as the same cryoprotectants (sucrose and 1,2 -propanediol). However, hyaluronan is included only in the proposed devices. In addition, the subject devices have a different buffer base compared to the predicate devices. The addition of hyaluronan in the subject device and the different buffer base do not raise any different types of safety and effectiveness questions.

The subject and predicate devices have similar specifications, including pH, osmolality, endotoxin levels and MEA performance. In addition, both the subject and predicate devices are sterilized by aseptic filtration. The subject device includes one additional specification for the MEA analysis is evaluated for the proposed devices. However, this does not represent a difference in technological characteristics and does not raise any different types of safety and effectiveness questions.

Non-Clinical Bench Testing

The following parameters were measured and evaluated to assure satisfactory operating performance of FreezeKit™ Cleave and ThawKit™ Cleave:

- pH at +20°C and ambient atmosphere
- Osmolality in mOsm/kg
- Sterility
- Bacterial Endotoxins (LAL assay) in EU/mL
- Mouse embryo assay (1-cell MEA) [% expanded blastocyst within 96h]
- Mouse embryo assay (1-cell MEA) [blastocyst cell number within 96h]

All bench tests performed met the predefined acceptance criteria.

Clinical Testing

A clinical evaluation was performed to assure satisfactory performance of FreezeKit™ Cleave and ThawKit™ Cleave. The testing assessed survival and development of frozen and thawed human 2PN embryos and cleavage-stage embryos after being cryopreserved with the subject devices as compared to the predicates. Results for the subject device demonstrated satisfactory survival and development of treated 2PN embryos.

Conclusions

The comparison of indications for use / intended purposes, product characteristics, specifications, composition and performance between the predicate devices (Cook IVF Cryopreservation Kit and Cook IVF Thawing Kit) and the proposed devices (FreezeKit™ Cleave and ThawKit™ Cleave) demonstrates that they are substantially equivalent. Although there are differences in the terminology of the indications for use, as well as minor differences in the composition, none of these differences render the subject device not substantially equivalent.

Pre-clinical and clinical evaluation studies demonstrate that the subject device performs comparably to the predicate device and support a determination of substantial equivalence.

Therefore, FreezeKit™ Cleave and ThawKit™ Cleave are as safe and effective as Cook IVF Cryopreservation Kit and Cook IVF Thawing Kit. FreezeKit™ Cleave and ThawKit™ Cleave are substantially equivalent to Cook IVF Cryopreservation Kit and Cook IVF Thawing Kit.