July 26, 2019

Vitrolife Sweden AB
Nina Arvidsson
Regulatory Affairs Manager
Gustaf Werners gata 2
SE 421 32 Vastra Frolunda
SWEDEN

Re: K183486
Trade/Device Name: RapidVit™ Oocyte, RapidWarm™ Oocyte
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: June 24, 2019
Received: June 26, 2019

Dear Nina Arvidsson:

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,

Sharon M. Andrews
Assistant Division 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)*
K183486

Device Name

RapidVit™ Oocyte, RapidWarm™ Oocyte

Indications for Use *(Describe)*

RapidVit™ Oocyte: Media for vitrification of human oocytes (MII).

RapidWarm™ Oocyte: Media for warming of vitrified human oocytes (MII).

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 (K183486)

1. Submitter Information

Submitted by: Vitrolife Sweden AB
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Contact Person: Nina Arvidsson
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2. Date Prepared

July 24, 2019

3. Device Identification

Trade Name: RapidVit™ Oocyte, RapidWarm™ Oocyte
Common Name: Oocyte Vitrification/Warming Kit
Regulatory Class: Class II
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Product Code: MQL (Media, Reproductive)

4. Predicate Device:

Vit Kit® - Freeze (Vitrification Freeze Kit), Vit Kit® - Thaw (Vitrification Thaw Kit) - (K160006) manufactured by Irvine Scientific. The predicate device has not been subject to a design related recall.

5. Device Description

Two sets of media are covered by this 510(k), the RapidVit™ Oocyte for vitrification of oocytes and the RapidWarm™ Oocyte for warming of vitrified oocytes. RapidVit™ Oocyte contains three medium solutions to be used sequentially during oocyte vitrification. RapidWarm™ Oocyte includes four medium solutions to be used sequentially during oocyte warming. The table below outlines the components contained in RapidVit™ Oocyte and RapidWarm™ Oocyte.

Component	Formulation characteristics	Utilization
Vitri 1™ Oocyte	Contains no cryoprotectants	First step of vitrification
Vitri 2™ Oocyte	Contains cryoprotectants (ethylene glycol [8%] and propanediol [8%])	Second step of vitrification
Vitri 3™ Oocyte	Contains (ethylene glycol [16%], propanediol [16%], and sucrose [0.442 M])	Third step of vitrification
Warm 1™ Oocyte	Contains sucrose (1 M)	First step of warming
Warm 2™ Oocyte	Contains sucrose (0.5 M)	Second step of warming
Warm 3™ Oocyte	Contains sucrose (0.25 M)	Third step of warming
Warm 4™ Oocyte	Contains no sucrose	Fourth step of warming

All media are aseptically filtered and filled in 10 ml plastic bottles and have a 25-week shelf-life under recommended storage conditions. They are stable for 2 weeks after opening of the packaging bottle, if stored under recommended conditions.

6. Indications for Use

RapidVit™ Oocyte: Media for vitrification of human oocytes (MII).
RapidWarm™ Oocyte: Media for warming of vitrified human oocytes (MII).

7. Substantial Equivalence Discussion

Device	K183486 (subject device)	K160006 (predicate device)
Indications for Use	RapidVit™ Oocyte - Media for vitrification of human oocytes (MII). RapidWarm™ Oocyte - Media for warming of vitrified human oocytes (MII).	Vit Kit® - Freeze (Vitrification Freeze Kit) is intended for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos. Vit Kit® - Thaw (Vitrification Thaw Kit) is intended for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.
pH	7.2-7.4	Vitrification media – 7.05-7.54 Warming media – 7.05-7.44
Osmolality (mOsm/kg)	Vitri 1™ Oocyte: 272-288 Vitri 2™ Oocyte: 3045-3355 Vitri 3™ Oocyte: 6530-7370 Warm 1™ Oocyte: 1450-1610 Warm 2™ Oocyte: 800-900	ES Freeze: 1055-1445 VS Freeze: 1100-1588 TS Thaw: 1732-1912 DS Thaw: 857-910 WS Thaw: 268-292

	Warm 3™ Oocyte: 560-600 Warm 4™ Oocyte: 272-288	
Key components in vitrification media	Amino acids MOPS Human Serum Albumin Ethylene glycol Sucrose Gentamicin Propanediol Hyaluronan	Medium 199 Dextran serum supplement Amino acids Ethylene glycol Sucrose Gentamicin DMSO
Key components in warming media	Amino acids Human Serum Albumin Sucrose Gentamicin Hyaluronan	Medium 199 Dextran serum supplement Amino acids Sucrose Gentamicin

Both subject and predicate devices are indicated for vitrification of oocytes and warming of vitrified human MII oocytes, while the predicate device is also indicated for vitrification of embryos (PN-blastocyst stages). Although the subject device has a more limited indication, the intended use (i.e., vitrification and warming of oocytes for use in assisted reproduction procedures) is the same.

The subject and predicate devices are different in technological characteristics, including pH, osmolality, and formulation. These differences do not raise different questions of safety and effectiveness, and are common in assisted reproduction technology media devices.

8. Summary of Non-Clinical Performance Testing

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

- pH testing per USP <791>
- Osmolality testing per USP <785>
- Aseptic filling validation study per ISO 11137-1:2006 and ISO 11137-2:2013
- Bacterial endotoxins testing per USP <85> (acceptance criterion: <0.5 EU/ml)
- Sterility testing per USP <71> (acceptance criterion: no microbial growth)
- Mouse Embryo Assay (MEA) using established protocol:

  One-cell mouse embryos were exposed sequentially to each vitrification solution and each warming solution using exposure conditions identical to the maximum exposure durations stated in the Instructions for Use. The embryos were then cultured at 37°C in an atmosphere containing 5% CO_2. The percentage of embryos developed to the expanded

blastocyst stage within 96 hours were assessed in comparison with the control group. The acceptance specification is "≥80% of embryos expand to the blastocyst stage by 96h."

- Shelf-life testing was conducted to ensure that the following product specifications are met at time zero and end of shelf-life (25 weeks): pH, osmolality, sterility, 1-cell MEA, and endotoxin.
- Stability testing was conducted to ensure that the following product specifications are met at two weeks after opening of packaging bottles: pH, osmolality, sterility, 1-cell MEA, and endotoxin.

9. Summary of Clinical Performance Testing

A clinical study was conducted to evaluate clinical performance of the subject device using 593 oocytes from 64 donors. The study showed the oocyte survival rate of 94% after vitrification (555/593), fertilization rate of 78% (434/555), Day 5 blastulation rate of 24% (102/434), Day 5/6 utilization rate of 35% (153/434), and clinical pregnancy (confirmed by fetal heartbeat) rate of 50% (27/54 recipients).

10. Conclusion

The subject and predicate devices have the same intended use and comparable technological characteristics. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.