January 4, 2019

Vitrolife Sweden AB
Nina Arvidsson
Regulatory Affairs Manager
Gustaf Werners gata 2
SE-421 32 Västra Frölunda
Sweden

Re: K181461
Trade/Device Name: Rapid-i™ Kit
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: II
Product Code: MQK
Dated: December 4, 2018
Received: December 7, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael T. Bailey -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)*
K181461

Device Name
Rapid-i™ Kit

Indications for Use *(Describe)*

Cryopreservation device intended to be used to contain, vitrify and maintain human embryos and/or 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.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K181461

1. Submitter Information

Submitter: Vitrolife Sweden AB
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SE-421 32 Västra Frölunda
Sweden

Contact Person: Nina Arvidsson
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2. Date Prepared:

January 3, 2019

3. Device Identification

Trade Name: Rapid-i™ Kit
Common Name: Cryopreservation Storage Device
Classification Name: Assisted Reproduction Labware
Regulation Number: 21 CFR 884.6160
Product Code: MQK (Labware, Assisted Reproduction)
Regulatory Class: II

4. Predicate Device:

Rapid-i™ Kit (K140207) manufactured by Vitrolife Sweden AB. This predicate device has not been subject to any design related recalls.

5. Device description:

Rapid-i™ Kit is a modified version of the predicate device (K140207). This device is a cryopreservation storage device intended for embryo/oocyte vitrification. Rapid-i™ Kit is provided sterile and is for single-use only. This device consists of the following items:

- Rapid-i Stick – A 80 mm long Polymethyl methacrylate (PMMA) stick with a 0.4 mm diameter hole located near the distal tip of the device. The hole on the stick is used to hold one to five embryos or oocytes for vitrification in a 30 nL drop of vitrification medium. Users suspend samples across the hole via surface tension. Therefore, the medium containing the samples only touches the periphery of the hole. The stick has one flat side that aids in correct orientation of the device during oocyte/embryo loading procedures.

- RapidStraw – A 130 mm long Mediprene straw equipped with a stainless steel weight to maintain device orientation in liquid nitrogen (LN). The straw has a flared open end to allow for insertion of the Rapid-i Stick. This component functions as a protective sleeve around the Rapid-i Stick to prevent direct contact with LN during loading and after sealing the open end with an ultrasonic sealing device.
- Stainless steel rod – This 115 mm long stainless steel rod resides within RapidStraw during pre-cooling procedures in LN. It aids in keeping RapidStraw straight in LN during pre-cooling. Rod removal occurs 20-30 seconds prior to Rapid-i Stick loading into the RapidStraw.

6. Indications for use:

Cryopreservation device intended to be used to contain, vitrify and maintain human embryos and/or oocytes (MII).

7. Substantial Equivalence Discussion

Devices	Subject device (K181461)	Predicate device (K140207)
Indications for Use	A cryopreservation device intended to be used to contain, vitrify and maintain human embryos and/or oocytes (MII).	A cryopreservation device designed to contain, vitrify and maintain 4-8 cell and blastocyst stage human embryos.
Design	Same as the predicate device	The stick has a tip where the samples are loaded in a 0.4 mm diameter hole. The stick is sealed within in a straw that contains a stainless steel weight to maintain device orientation in LN.
Dimension	- Rapid-i stick: 2mm × 80mm - RapidStraw: 3.40mm (OD)/2.40mm (ID) × 130mm - Stainless Steel Rod: 2.2mm × 115mm	- Rapid-i stick: 2mm × 80mm - RapidStraw: 3.45mm (OD)/2.45mm (ID) × 135mm - Stainless Steel Rod: 2.2mm × 115mm
Cooling rate	Same as the predicate device	1400°C/min (at -50°C)
Warming rate	Same as the predicate device	10000°C/min (at -50°C)
Device materials	Same as the predicate device	Polymethyl methacrylate (PMMA) Mediprene Stainless steel
Vitrification and warming methods	Same as the predicate device	Precool a straw (with steel rod inserted) with the open end extending above the LN level. A 30 nL drop of vitrification medium holding samples is loaded in a sample hole in the stick. The stick is then inserted into the pre-cooled straw (after steel rod removal) to vitrify samples. The end of the straw is sealed and the device is stored in LN.

The subject device is indicated to contain, vitrify and maintain human embryos and oocytes (MII), whereas the predicate device is indicated to vitrify and maintain 4-8 cell and blastocyst stage embryos. Inclusion of the oocyte indication and expansion of the embryo indication to also include 2 PN embryos does not represent a new intended use because processing of the embryos or oocytes is applicable to same patient population with same clinical needs – infertility treatment or fertility preservation. Therefore, the subject and predicate devices have the same intended use.

The subject and predicate devices have similar technological characteristics. The only difference between the subject and predicate device is that the subject RapidStraw has a length of 130 mm and 3.40 mm OD/2.40 mm ID whereas the predicate RapidStraw has a length of 135 mm and 3.45 mm OD/2.45 mm ID. This difference is minor and does not raise different questions of safety and effectiveness as compared to the predicate device.

8. Summary of Non-Clinical Performance Data

Non-clinical performance testing was conducted to support substantial equivalence to the predicate device. Rapid-i™ Kit passed all the tests shown below in accordance with internal requirements and/or applicable standards.

- Dimensional Testing per predefined design specifications.
- Bacterial Endotoxin Testing – <1.0 EU/device per USP <85> and ANSI/AAMI ST72:2002/(R)2010
- Mouse Embryo Assay (MEA) – ≥80% of 1-cell embryos developed to blastocysts at 96 hours
- Shelf-life Testing:
  - Package integrity testing:
    - Dye penetration test of sterile packages per ASTM F1929-15
    - Seal strength of sterile packages per ASTM F88/F88M-15
    - Visual inspection per ASTM F1886/F1886M-16
  - Dimensional testing, endotoxin testing and MEA in accordance with the methods and acceptance criteria mentioned above

In addition, information regarding cooling/warming rate testing and sterilization validation per ISO 11135:2014 and ISO 10993-7:2008 provided in K140207 was leveraged to support substantial equivalence.

9. Summary of Clinical Performance Data

Data from clinical studies using the Rapid-i™ Kit were used to demonstrate the ability of the subject device to be used as a cryopreservation device for oocytes and 2 PN embryos.

- Vitrification of 2PN embryos:

  Of 1618 2 PN embryos vitrified with Rapid-i™ Kit, 1458 (90.1%) survived after warming. Five hundred ten (510) embryo transfers were conducted using the embryos cultured for 1-3 days (418 transfers) or for 4-5 days (92 transfers). The clinical pregnancy rate resulting from the embryos cultured for 1-3 days was 25.1%. The clinical pregnancy rate resulting from the embryos cultured for 4-5 days was 36.3%.

- Vitrification of oocytes:

  - In one study, 94% (555/593) oocytes vitrified with Rapid-i™ Kit survived after warming. The fertilization rate, day 2 cleavage rate, day 5 blastulation rate were 78% (434/555), 95% (414/434) and 24% (102/434), respectively. Of the 54 blastocyst stage embryo transfers, 27 (50%) resulted in a clinical pregnancy.

  - In another study, the survival rate and fertilization rate of oocytes vitrified with the Rapid-i™ Kit were 93.7% and 58.5%, respectively. Of the 40 embryo transfers performed, 16 (40%) resulted in clinical pregnancy.

  - In a published journal article, 90.5% (374/413) oocytes vitrified with Rapid-i™ Kit survived after warming. The fertilization rate of survived oocytes was 64.2% (240/374). The cleavage rate on day 2 was 90.4% (217/240). Of the 44 embryo transfers performed, 18 (40.9%) resulted in clinical pregnancy. [Ref: Gook et al. (2016) Closed vitrification of human oocytes and blastocysts: outcomes from a series of clinical cases. J Assist Reprod Genet 33:1247-1252]

10. Conclusions:

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 devices are substantially equivalent to the predicate device.