November 21, 2017

Vitrolife Sweden AB
% Greg Holland
Regulatory Specialist
Regulatory Specialist, Inc.
3722 Ave. Sausalito
Irvine, CA 92606

Re: K172050
Trade/Device Name: Follicle Aspiration Set, Reduced Single Lumen
Regulation Number: 21 CFR§ 884.6100
Regulation Name: Assisted Reproduction Needles
Regulatory Class: II
Product Code: MQE
Dated: October 16, 2017
Received: October 19, 2017

Dear Greg Holland:

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.

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.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172050

Device Name
Follicle Aspiration Set, Reduced Single Lumen

Indications for Use *(Describe)*
Intended for flushing and/or aspiration of oocytes from ovarian follicles.

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.

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510(k) Summary – K172050

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Date Prepared	November 17, 2017
Trade Name	Follicle Aspiration Set, Reduced Single Lumen
Common Name	Oocyte Retrieval Needle
Classification Name	Assisted Reproduction Needles
Regulation Number	884.6100
Regulatory Class	II
Product Code	MQE (Needle, Assisted Reproduction)
Predicate	Follicle Aspiration Set, Reduced Single Lumen (K082727). This predicate device has not been subjected to a design-related recall.

Device Description:

The Follicle Aspiration Set, Reduced Single Lumen proposed in this submission is intended for ultrasound-guided transvaginal aspiration and flushing of oocytes from ovarian follicles. This product is comprised of the following components:

- A stainless steel needle
- A silicone cork to be pushed into the opening of a sampling tube
- A length of TPE-O tubing for aspiration and flushing
- An adapter for flushing

The subject device is provided sterile and is for single use only. It comes in four versions with the same design but different dimensions, as described below.

REF	Needle Body [mm]			Needle Tip [mm]			Aspiration Tubing [mm]		
	OD	ID	L	OD	ID	L	OD	ID	L
17175	1.4	1.2	250	0.9	0.6	50	2.22	1.33	600
17176	1.4	1.2	250	0.9	0.6	50	2.22	1.33	900
17177	1.4	1.2	300	0.9	0.6	50	2.22	1.33	600
17178	1.4	1.2	300	0.9	0.6	50	2.22	1.33	900
The cork (REF 21014) has OD of 1.7 mm on the top and 13 mm in the bottom and length of 22 mm.									

Indications for Use:

Intended for flushing and/or aspiration of oocytes from ovarian follicles.

Comparison of Intended Use and Technological Characteristics of Subject and Predicate Devices:

Devices	K172075 (subject device)	K082727 (predicate device)
Intended use		
Indications for Use	Same as predicate	Intended for flushing and/or aspiration of oocytes from ovarian follicles.
Technological characteristics - Design		
Lumen type	Same as predicate	Single lumen
Needle length	Tip - 50 mm; Body - 250/300 mm	Tip - 40 mm; Body - 260/310 mm
Needle Outer Diameter	Same as predicate	Tip - 0.9 mm; Body - 1.4 mm
Needle Inner Diameter	Same as predicate	Tip - 0.6 mm; Body - 1.2 mm
Aspiration tube length	600/900 mm	600 mm
Tubing Outer diameter	2.22 mm	1.95 mm
Tubing Inner diameter	1.33 mm	1.35 mm
Cannula	Bent cannula on cork	Straight cannula mounted on cork
Cork and cannula geometry	Allows connection of a vacuum pump	Requires a connection/cork adapter
Technological characteristics - Materials		
Aspiration needle	Same as predicate	Stainless steel
Needle grip	Same as predicate	Stainless steel
Aspiration tubing	Polyolefin based TPE (TPE-0)	Teflon
Cork	Same as predicate	Silicone
Cork adapter	Acrylonitrile Butadiene Styrene (ABS) Sinkral	Stainless steel
Cannula Luer	Methylmethacrylate Acrylonitrile Butadiene Styrene (MABS)	Polypropylene
Cannula for flushing	Same as predicate	Stainless steel
Protective sheath	Polypropylene	N/A
Bonding material	Same as predicate	Epoxy resin

The subject and predicate devices have the same intended use – flushing and/or aspiration of oocytes from ovarian follicles.

There are differences in design and materials used in different components between the subject and predicate devices. However, these differences do not raise different questions of safety and effectiveness. Similar features are also common in other cleared oocyte retrieval needles.

Performance Testing:

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

- Sterilization Validation Study per ISO 11137-2:2013
- Endotoxin Testing using LAL method per USP<85> to demonstrate that the subject device meets acceptance criterion of ≤1.2 EU/ device
- Breakage and Elasticity Testing to demonstrate that the stainless needle of the subject device meets the requirements in ISO 9626:2016
- Accelerated shelf-life testing to demonstrate that the subject device meets the following performance criteria at the end of three-year shelf-life:
  * Mouse embryo assay (MEA) – 1-Cell MEA: ≥80% embryos expanded to blastocysts within 96 hours

    One-cell mouse embryos were exposed to subject device extracts and cultured at 37°C in an atmosphere containing 5% CO_2. The percent of embryos developed to the expanded blastocyst stage within 96 hours were assessed in comparison with the control group.
  * Visual Inspection per ASTM F1886/F1886M-09
  * Dye Penetration Testing per ASTM F1929-12
  * Seal Strength Testing per ASTM F88/F88M-09
  * Vacuum Testing – Assessment of device function under vacuum pressure at -500 mmHg. Devices were shown to operate as intended without signs of damage
  * Flow Testing – Testing was conducted to assess that flow rates were within anticipated ranges under intended use conditions
  * Tensile Strength Testing – Testing was conducted to assess that tensile strength at joints were within anticipated ranges under intended use conditions

Conclusions

The results of non-clinical performance testing described above demonstrate that the subject device is as safe and effective as the predicate device and supports a determination of substantial equivalence.