DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 14, 2017

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

Re: K161970
Trade/Device Name: Follicle Aspiration Set
Regulation Number: 21 CFR§ 884.6100
Regulation Name: Assisted Reproduction Needles
Regulatory Class: II
Product Code: MQE
Dated: April 28, 2017
Received: May 1, 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.

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,

Charles Viviano -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161970

Device Name
Follicle Aspiration Set

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.

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510(k) Summary – K161970

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Summary Date	June 14, 2017
Trade Name	Follicle Aspiration Set (See the Device Description section below for device versions included in this submission)
Common Name	Oocyte Retrieval Needle
Classification Name	Assisted Reproduction Needles
Regulation Number	884.6100
Class	II
Panel	Obstetrics/Gynecology
Product Code	MQE (Needle, Assisted Reproduction)
Predicate Device	K991273, Swemed Follicle Aspiration Set, Double Lumen Swemed Follicle Aspiration Set, Single Lumen Swemed Follicle Aspiration Luer Needle

The predicate device has not been subjected to a recall.

Device Description:

Follicle Aspiration Sets included in this submission are intended for ultrasound-guided transvaginal aspiration and flushing of oocytes from ovarian follicles. Four types of Follicle Aspiration Sets are included in this submission, and are described in more detail below.

The Follicle Aspiration Sets are radiation sterilized and are for single use only. The materials used in these devices include: stainless steel, TPE-O tubing, silicone, medical grade adhesive, polypropylene, and methyl methacrylate acrylonitrile butadiene styrene.

Follicle Aspiration Set, Single Lumen: This device consists of a single-lumen stainless steel needle, aspiration tubing, and a silicone rubber cork for attachment to a collection tube. One version (17132) also includes vacuum tubing attached to the silicone rubber cork for attachment to the vacuum pump used for aspiration. This device also includes an adapter for flushing of ovarian follicles and removal of blockages. The needles for the majority of the versions of this device type include echogenic markings at the tip of the needle to aid in visualization during aspiration procedures. The table below shows the specific features of the different versions of this device:

REF	Dimension					
	Needle			Tubing		
	OD [mm]	ID [mm]	Length [mm]	OD [mm]	ID [mm]	Length [mm]
17103	1.4	1.0	300	2.22	1.33	400
17107	1.4	1.0	300	2.22	1.33	600
17112	1.4	1.0	300	2.22	1.33	900
17125	1.4	1.0	330	2.22	1.33	900
17132	1.4	1.0	350	2.22	1.33	600/600
17156	1.4	1.0	350	2.22	1.33	600
17130	1.4	1.0	350	2.22	1.33	900
17119	1.6	1.1	250	2.32	1.53	600
17126	1.6	1.1	250	2.32	1.53	900
17113	1.6	1.1	300	2.32	1.53	400
17116	1.6	1.1	300	2.32	1.53	600
17120	1.6	1.1	300	2.32	1.53	900
17145	1.6	1.1	350	2.32	1.53	400
17157	1.6	1.1	350	2.32	1.53	600
17104	1.6	1.1	350	2.32	1.53	900
17183*	1.4	1.0	350	2.22	1.33	750
17185	1.2	1.0	350	2.32	1.43	600
17186	1.2	1.0	350	2.32	1.43	900

*This version of the device does not include echogenic markings.

Follicle Aspiration Set, Double Lumen: This device consists of a double lumen stainless steel needle, tubing for flushing of ovarian follicles and removal of blockages, tubing for aspiration, and a silicone rubber cork for attachment to a collection tube. One version (17129) also includes vacuum tubing attached to the silicone rubber cork for attachment to the vacuum pump used for aspiration. The needles for these versions of the device include echogenic markings at the tip of the needle to aid in visualization

during aspiration procedures. The table below shows the specific features of the different versions of this device:

REF	Dimension														
	Needle						Tubing								
	Outer			Inner			Aspiration tube			Flush tube			Vacuum tube		
	OD [mm]	ID [mm]	L [mm]	OD [mm]	ID [mm]	L [mm]	OD [mm]	ID [mm]	L [mm]	OD [mm]	ID [mm]	L [mm]	OD [mm]	ID [mm]	L [mm]
17151	1.5	1.3	350	1.1	0.90	400	2.32	1.43	600	2.22	1.33	600	-	-	-
17102	1.5	1.3	350	1.1	0.90	400	2.32	1.43	1000	2.22	1.33	1000	-	-	-
17150	1.65	1.45	250	1.2	1.0	300	2.32	1.43	400	2.22	1.33	400	-	-	-
17105	1.65	1.45	300	1.2	1.0	350	2.32	1.43	900	2.22	1.33	900	-	-	-
17108	1.65	1.45	300	1.2	1.0	350	2.32	1.43	400	2.22	1.33	400	-	-	-
17131	1.65	1.45	300	1.2	1.0	350	2.32	1.43	400	2.22	1.33	900	-	-	-
17158	1.65	1.45	300	1.2	1.0	350	2.32	1.43	600	2.22	1.33	400	-	-	-
17111	1.65	1.45	300	1.2	1.0	350	2.32	1.43	600	2.22	1.33	600	-	-	-
17129	1.65	1.45	300	1.2	1.0	350	2.32	1.43	900	2.22	1.33	900	2.32	1.43	900
17161	1.65	1.45	350	1.2	1.0	400	2.32	1.43	400	2.22	1.33	400	-	-	-
17109	1.65	1.45	350	1.2	1.0	400	2.32	1.43	600	2.22	1.33	600	-	-	-
17148	1.65	1.45	350	1.2	1.0	400	2.32	1.43	900	2.22	1.33	600	-	-	-
17114	1.65	1.45	350	1.2	1.0	400	2.32	1.43	900	2.22	1.33	900	-	-	-
17168	1.65	1.45	350	1.2	1.0	400	2.32	1.43	1000	2.22	1.33	1000	-	-	-

Follicle Aspiration Set, Single Lumen Luer with Tubing: This device consists of a single lumen stainless steel needle, and aspiration tubing with a luer connection at the end. The needle is provided with echogenic markings at the tip of the needle to aid in visualization during aspiration procedures. The table below shows the specific features of this device:

REF	**Dimension**					
	Needle			**Tubing**		
	OD [mm]	ID [mm]	Length [mm]	OD [mm]	ID [mm]	Length [mm]
17123	1.5	1.2	300	2.32	1.43	600

Follicle Aspiration Set, Single Lumen, Luer: This device consists of a single lumen stainless steel needle with a luer connection at the base of the needle. The needle is provided with echogenic markings at the tip of the needle to aid in visualization during aspiration procedures. The table below shows the specific features of the different versions of this device:

REF	**Dimension**		
	OD [mm]	ID [mm]	Length [mm]
17154	1.2	0.8	300
17152	1.4	1.2	250
17140	1.4	1.2	300
17147	1.6	1.3	300
17137	1.6	1.3	350

Indication 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:

Device & Predicate Device(s):	K161970	K991273
General Device Characteristics		
Indication for use	Intended for flushing and/or aspiration of oocytes from ovarian follicles	The swemed follicle aspiration set, double lumen, swemed follicle aspiration set, single lumen, and swemed follicle aspiration luer needle and intended to obtain gametes from the body are specially indicated for flushing and/or aspiration of oocytes from ovarian follicles.
Materials		
Aspiration needle	Stainless steel	Stainless steel
Needle grip	Stainless steel	Stainless steel
Aspiration tubing	Polyolefin based TPE (TPE-0)	Teflon
Cork	Silicone	Silicone
Cork adapter	Bent blunt cannula mounted on the cork Adapter/ blunt cannula is not needed for a syringe with luer slip. Syringe with luer lock – new adapter is needed to be able to connect to the cork	Straight Blunt Stainless steel cannula (can be used to connect a vacuum pump) An adapter (a blunt cannula) is always needed to be able to connect a syringe to the cork.
Cannula Luer	Methyl Methacrylate Acrylonitrile Butadiene Styrene	Polypropylene luer lock connection
Cannula for flushing	Stainless steel	Stainless steel
Protective sheath	Polypropylene	Not provided

Bonding	Epoxy resin	Epoxy resin
Packaging	Tyvek+ Polyethlene/ Polypropylene (clear transparent)	Paper + Polyethlene/Polypropylene (green transparent)
Sterility	Radiation	Steam
Mouse Embryo Assay (MEA)	1-Cell MEA: ≥ 80 % expanded blastocysts within 96 hours.	2-Cell MEA
Endotoxins	≤ 1.2 EU/ device	≤ 1.2 EU/ device
Design Features		
Follicle Aspiration set, single lumen		
Needle length (straight)	250,300, 330, 350 (mm)	200, 250, 300, 350 (mm)
Needle Outer Diameter	1.2, 1.4, 1.6 (mm)	1.2, 1.4 , 1.5 , 1.6 (mm)
Needle Inner Diameter	1.0, 1.1, 1.2 (mm)	0.8-1.3 (mm)
Aspiration tube length	400, 600, 750, 900 (mm)	400, 600, 900
Tubing Outer diameter	2.22 & 2.32 (mm)	1.67, 1.95 (mm)
Tubing Inner diameter	1.33, 1.43, 1.53 (mm)	1.07, 1.35 (mm)
Vacuum Tubing	600 mm	NA
Follicle Aspiration set, double lumen		
Needle length (Inner and outer needle) -Outer -Inner	250, 300 & 350 (mm) 300, 350 & 400 (mm)	250-350 (mm)
Outer Needle Diameter -Outer -Inner	- 1.5 & 1.65 (mm) -1.3 & 1.45 (mm)	1.2, 1.6 (mm) 0.8, 1.0
Inner Needle Diameter -Outer -Inner	- 1.1 & 1.2 (mm) - 0.9 & 1.0 (mm)	NA
Aspiration tube length	400, 600, 900, 1000 (mm)	400, 600, 900
Aspiration Tubing Outer diameter	2.32 (mm)	1.67, 1.95 (mm)
Aspiration Tubing Inner diameter	1.43 (mm)	1.07 , 1.35 (mm)
End of Flushing tube	Blunt cannula OD/ID 1.5/1.3 mm	Hub with hole 1.2 mm

Flush Tube Length	400, 600, 900, 1000 (mm)	300, 400,600, 900
Flush Tube Outer Diameter	2.22 (mm)	Not provided
Flush Tube Inner Diameter	1.33 (mm)	Not provided
Vacuum Tube	900 (mm)	Not provided
Vacuum Outer Diameter	2.32 (mm)	Not provided
Vacuum Inner Diameter	1.43 (mm)	Not provided
Follicle Aspiration Set, Single Lumen, Luer with Tubing		
Needle Length Needle Outer Diameter Needle Inner Diameter	300 (mm) 1.5 (mm) 1.2 (mm)	200, 250, 300, 350 (mm) 1.2, 1.4 , 1.5 , 1.6 (mm) 0.8-1.3 (mm)
Tubing Length Tubing Outer Diameter Tubing Inner Diameter	600 (mm) 2.32 (mm) 1.43 (mm)	200, 250, 300, 350 (mm) 1.2, 1.4 , 1.5 , 1.6 (mm) 0.8-1.3 (mm)
Leur Connector on Aspiration Tubing	Yes	No
Follicle Aspiration Set, Single Lumen, Luer		
Needle Length Needle Outer Diameter Needle Inner Diameter	250,300,350 (mm) 1.2,1.4,1.6 (mm) 0.8,1.2,1.3 (mm)	250, 300, 350 (mm) 1.2, 1.4, 1.6 (mm) 0.8, 1.0 1.2, 1.3 (mm)

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The indications for use statements for the subject and predicate devices are similar in that they are both for use in flushing and retrieval of oocytes from ovarian follicles. Therefore, these devices have the same intended uses.

The subject and predicate devices are similar in some technological features, including design (e.g., needle material, needle length, lumen type, tip shape, cork material, etc.). However, there are a number of differences between the subject and predicate device that are described below:

- Device materials – Some of the device materials (e.g., tubing, luer, etc.) are not the same. Materials differences are common in Assisted Reproduction Technology (ART) devices and do not raise different questions of safety and effectiveness, and can be addressed through testing (e.g., MEA, biocompatibility, performance).

- Tubing Dimensions - Dimensions of all the design types are slightly different from the predicate device (e.g., length and diameter). Differences in dimensions noted in the table above do not raise different questions of safety and effectiveness (e.g., ability to withstand vacuum pressures during use, etc.) and differences can be assessed through performance testing.

- Needle Dimensions – There is slight difference in needle length and diameter for all device types. Variations in needle length occur in ART oocyte aspiration needles and do not raise different questions of safety or effectiveness (e.g., sufficient length to aspirate oocytes, diameter compatible with dimensions of oocytes). Performance data can be used to support these types of differences

- Device design – 1) The subject device has a bent (45 degrees) cannula mounted on cork for easier access for connection of a vacuum pump, whereas the predicate device has a straight cannula. 2) For the double lumen aspiration kit, the subject device has a blunt cannula at the end of the flushing tube, while the predicate device has a luer fitting. 3) The subject device has an additional device type, Single Lumen Luer with Tubing, while the corresponding predicate device is described as a Single Lumen (i.e., no leur at end of tubing) . The modification of adding leur fitting to the end of the tubing, modifying the cork and cannula design/geometry, and the addition of a blunt cannula do not raise different questions of safety and effectiveness and differences can be assessed through performance testing. . The Single Lumen Luer with tubing has not been previously cleared in the predicate; however, the technology is similar to the devices within this submission and previously cleared devices with the same intended use.

- Packaging material- the subject device uses Tyvek and clear polyethylene/polypropylene, whereas the predicate device uses paper and green transparent material. The material differences in packaging are common and do not raise different questions of safety and effectiveness, and can be addressed through testing (e.g., package integrity).

- The subject device MEA assay has an acceptance criterion of ≥ 80% expanded blastocyst within 96 hours using the one-cell MEA, while the predicate device conducted a two-cell MEA. Both methods are acceptable to support ART devices and do not raise different questions of safety or effectiveness.

Performance Testing:

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

- Sterilization Validation per ISO 11137-2:2013.
- Endotoxin testing (USP<85>, LAL) - ≤1.2 EU/ device
- Mouse embryo assay (MEA) – 1-Cell MEA: ≥80% expanded 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.
- 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.

- Mechanical Testing of Needles
  - Breakage, Bend, Stiffness per ISO 9626: 2016.
- Tensile Strength Testing
- Biocompatibility Testing:
  - Cytotoxicity testing per 10993-5:2009
  - Guinea Pig Maximization Sensitization testing per ISO 10993-10:2010
  - Intracutaneous Reactivity testing per ISO 10993-10:2010

  Testing showed that the device extracts assessed were non-cytotoxic, non-sensitizing, and non-irritating.
- Shelf-life studies (accelerated) were conducted to ensure that the following acceptance criteria are met for the for devices over their 3 years shelf-life:
  - 1-cell MEA – ≥80% expanded blastocysts within 96 hours
  - Standard Test Method for Seal Strength of Flexible Barrier Materials per ASTM F88 / F88M – 09
  - Dye Penetration per ASTM F1929 – 12
  - Visual Inspection per ASTM F1886 / F1886M – 09
  - Tensile Strength Testing

Conclusions from Non-Clinical Performance Data

The results of the performance testing described above demonstrate that the Follicle Aspiration Set is as safe and effective as the predicate device and supports a determination of substantial equivalence.