February 22, 2024

Zhejiang Horizon Medical Technology Co., Ltd.
Wu Tang
RA Supervisor
Room 219, 2nd floor, Building 9, 1303 Asia-Pacific Road
Daqiao Town, Nanhu District
Jiaxing, Zhejiang 314006
CHINA

Re: K232163
Trade/Device Name: Lotus Single Lumen Ovum Aspiration Needle;
Lotus Double Lumen Ovum Aspiration Needle
Regulation Number: 21 CFR 884.6100
Regulation Name: Assisted Reproduction Needles
Regulatory Class: II
Product Code: MQE
Received: January 24, 2024

Dear Wu Tang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Michael T. Bailey -S

For
Monica D. Garcia, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232163

Device Name
Lotus Single Lumen Ovum Aspiration Needle; Lotus Double Lumen Ovum Aspiration Needle

Indications for Use *(Describe)*
Lotus Single Lumen Ovum Aspiration Needle is used for ultrasound guided transvaginal aspiration of oocytes from ovarian follicles for patients undergoing Assisted Reproductive procedures.

Lotus Double Lumen Ovum Aspiration Needle is used for ultrasound guided transvaginal aspiration and flushing of oocytes from ovarian follicles for patients undergoing Assisted Reproductive procedures.

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
K232163

1. Submitter Information

Applicant: Zhejiang Horizon Medical Technology Co., Ltd.
Address: Room 219, 2nd floor, Building 9, 1303 Asia-Pacific Road, Daqiao Town, Nanhu District, Jiaxing City, Zhejiang Province, P. R. China.

2. Submission Correspondent

Company: Zhejiang Horizon Medical Technology Co., Ltd.
Contact: Tang Wu
Phone: +86-21-38954600-59403
Email: wu.tang@microport.com

3. Date prepared:

February 20, 2024

4. Device Information

Device Name:	Lotus Single Lumen Ovum Aspiration Needle; Lotus Double Lumen Ovum Aspiration Needle
Common Name:	Assisted Reproduction Needles
Regulation Number:	21 CFR 884.6100
Regulation Name:	Assisted Reproduction Needles
Product Code:	MQE (Needle, Assisted Reproduction)
Regulatory Class:	Class II

5. Predicate Device Information

Device Name:	Wallace Dual Lumen Oocyte Recovery System
510(k) Number:	K191291
Sponsor:	CooperSurgical Inc.

The predicate device has not been subject to a design-related recall.

6. Device Description

The subject devices are single use sterile devices used for ultrasound-guided transvaginal aspiration of oocytes from ovarian follicles.

The Lotus Single Lumen Ovum Aspiration Needle consists of a stainless steel needle with a handle, which is connected to an aspiration tube with a silicone stopper at the other end. The stopper can fit onto a test tube where the oocytes are collected. The stopper is connected to a vacuum tube with a vacuum tubing connector at the other end. The vacuum tubing connector is a standard luer lock connector that enables connection to a vacuum pump to provide aspiration suction. The Lotus Single

Lumen Ovum Aspiration Needle is 35 cm in length and has device variations from 21 to 16 gauge with aspiration tubing of 600 or 900 mm in length.

The Lotus Double Lumen Ovum Aspiration Needle consists of a stainless steel needle with a Y-shaped handle. The Y-shaped handle has two ports: the central port through which oocytes are aspirated via the aspiration lumen, and a secondary side port to allow flushing of follicles via the flushing lumen. The central port is connected to an aspiration tube with a silicone stopper at the other end. The stopper can fit onto a test tube where the oocytes are collected. The stopper has a vacuum connector that is a standard luer lock connector that enables connection to a vacuum pump to provide aspiration suction. The side port is connected to a flushing tube with a flushing connector at the other end, which is a standard luer lock connector that can be connected to a compatible syringe for flushing of follicles. The Lotus Double Lumen Ovum Aspiration Needle is 17 gauge with an aspiration tubing length of 900 mm and with device variations of 30 or 35 mm needle length and flushing tubing of 700 or 1000 mm in length.

7. Indications for Use Statement

Lotus Single Lumen Ovum Aspiration Needle is used for ultrasound guided transvaginal aspiration of oocytes from ovarian follicles for patients undergoing Assisted Reproductive procedures.

Lotus Double Lumen Ovum Aspiration Needle is used for ultrasound guided transvaginal aspiration and flushing of oocytes from ovarian follicles for patients undergoing Assisted Reproductive procedures.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below includes a comparison of the intended use and technological characteristics of the subject and predicate devices.

	K232163	**K191291**	**Comparison**
Manufacturer	Zhejiang Horizon Medical Technology Co.,	CooperSurgical	--
Classification	Class II	Class II	Same
Product Code	MQE	MQE	Same
Regulation	21 CFR 884.6100	21 CFR 884.6100	Same
Indications for Use	Lotus Single Lumen Ovum Aspiration Needle is used for ultrasound guided transvaginal aspiration of oocytes from ovarian follicles for patients undergoing Assisted Reproductive procedures. Lotus Double Lumen Ovum Aspiration Needle is used for ultrasound guided	The Wallace Dual Lumen Oocyte Recovery System is a sterile, single-use device for ultrasonic-guided transvaginal collection of oocytes from the ovarian follicles.	There are differences between the subject and predicate device indications for use statements; however, the subject and predicate devices have the same intended use (i.e., to recover oocytes from ovarian follicles for use in assisted reproduction procedures).

	transvaginal aspiration and flushing of oocytes from ovarian follicles for patients undergoing Assisted Reproductive procedures.		
Lumen Type	Single and Double	Double	Different
Materials	Single – Stainless steel (304), FEP, PC, Silicone Double – Stainless steel (304), FEP, PC, Silicone, HDPE	Stainless steel, methacrylate butadiene styrene (MBS), silicone, polyurethane, polycarbonate, Nylon, acrylonitrile butadiene, styrene (ABS)	Different
Needle Gauge	Single – 16G to 21G Double – 17G	16G to 17G	Different
Needle Length	Single – 350 mm Double – 300 mm to 350 mm	330 mm	Different
Echogenic Markers	Yes	Yes	Same
Aspiration Tubing Length	Single – 600 mm to 900 mm Double – 900 mm	500 mm, 750 mm, 950 mm	Different
Flushing Tubing Length	700 and 1000 mm	700 mm	Different
Fitting	Single – Silicone stopper with vacuum tubing terminating in a leur vacuum pump connector. Double – Silicone stopper attached to leur vacuum connector for vacuum tubing connection.	Silicone bung that allows connection to sample tube. Bung is connected to vacuum tubing that allows connection to a vacuum source	Different
Sterilization Method	EO	EO	Same
Single/Repeat Use	Single Use	Single Use	Same
MEA	1-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours after a 30 minute exposure to the	1-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours.	Different

	Lotus Single Lumen Ovum Aspiration Needle; Lotus Double Lumen Ovum Aspiration Needle.		
Endotoxin	<20 EU per device	≤ 20 EU per device	Same
Shelf Life	3 years	2 years	Different

As shown in the table above, there are differences in the indications for use statements and technological features of the subject and predicate devices. However, the subject and predicate device have the same intended use (i.e., to recover oocytes from ovarian follicles for use in assisted reproduction procedures). In addition, the technological differences between the subject and the predicate device include differences in single/double lumen options, materials, needle gauge/length, aspiration tube length, fit, and shelf-life duration. These technological differences do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility:
Biocompatibility testing was performed in accordance with the 2023 FDA guidance document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process."* Testing included the following:

- Cytotoxicity (ISO 10993-5:2009/R 2014)
- Sensitization (ISO 10993-10:2010/R 2014)
- Intracutaneous Irritation (ISO 10993-23:2021)

The results of testing demonstrate that the subject devices are non-cytotoxic, non-irritating, and non-sensitizing.

Sterilization Testing:
Sterilization information was provided in accordance with the 2016 FDA guidance "Submission and Review of Sterility Information in Premarket Notification (510(k) Submissions for Devices Labeled as Sterile." The subject devices are subjected to an Ethylene Oxide (EO) sterilization process to achieve a Sterility Assurance Level (SAL) of 10^{-6}. The sterilization cycle was validated per the half-cycle method in accordance with ISO 11135:2014.

Ethylene oxide and ethylene chlorohydrin residual testing was conducted per ISO 10993-7: 2008/(R)2012.

Simulated Transportation:
Simulated transportation was performed after accelerated aging per ASTM D4169-22, *Standard Practice for Performance Testing of Shipping Containers and Systems*.

Stability and Shelf Life:
The following tests were completed to demonstrate that the subject devices maintained their performance in newly manufactured devices and after 3-years of accelerated aging per ASTM F1980-16 and simulated transportation:

- Mouse embryo assay (MEA) – Testing conducted in accordance with the 2021 FDA guidance "Mouse Embryo Assay for Assisted Reproduction Technology Devices." The acceptance criterion for the 1-Cell MEA was ≥80% embryos expanded to blastocyst at 96 hours after 30 minute exposure to the Lotus Single Lumen Ovum Aspiration Needle; Lotus Double Lumen Ovum Aspiration Needle.
- Endotoxin - Evaluation performed using the Gel-Clot Limulus Amoebocyte Lysate (LAL) method per ANSI/AAMI ST72:2011 and USP <85>. The acceptance criterion was ≤ 20 EU/device.
- Package Integrity Testing:
  - F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
  - ASTM F88/F88-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
  - ASTM F1929-15 Standard Test Method for Detecting Seal Leaks In Porous Medical Packaging by Dye Penetration
- Mechanical Performance Testing:
  - Appearance
  - Dimensional verification/validation
  - Needle stiffness, breakage resistance, and corrosion resistance per ISO 9626:2016
  - Tip penetration force, needle bond strength, and flow rate per ISO 7864:2016
  - Ultrasound detectability
  - Tubing bond strength, leak, and aspiration test per EN1618
  - Component compatibility (connectors and stoppers)

10. Conclusion

The results of the performance testing described above demonstrate that the subject devices are as safe and effective as the predicate device and support a determination of substantial equivalence.