December 16, 2022

Shanghai Horizon Medical Technology Co., Ltd.
℅ Zhixuan Zhang
Senior Supervisor of Regulatory Affairs
MicroPort Group Co., Ltd.
1601 ZhangDong Rd., ZJ Hi-Tech Park
Pudong New District
Shanghai, 201203
China

Re: K220010
Trade/Device Name: Daylily Single Use Sterile Embryo Transfer Catheters (Type I [ETC-1018 S, ETC-1018 L, ETC-1024 S, ETC-1024 L], Type II [ETC-2018 S, ETC-2018 L, ETC-2024 S, ETC-2024 L], Type III [ETC-3018 S, ETC-3018 L, ETC-3024 S, ETC-3024 L, ETC-3024 S-X, ETC-3024 L-X], and Type IV [ETC-4018 S, ETC-4018 L, ETC-4024 S, ETC-4024 L, ETC-4024 S-X, ETC-4024 L-X])
Regulation Number: 21 CFR§ 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: II
Product Code: MQF
Dated: November 14, 2022
Received: November 16, 2022

Dear Zhixuan Zhang:

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,

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)*
K220010

Device Name
Daylily Single Use Sterile Embryo Transfer Catheters (Type I [ETC-1018 S, ETC-1018 L, ETC-1024 S, ETC-1024 L], Type II [ETC-2018 S, ETC-2018 L, ETC-2024 S, ETC-2024 L], Type III [ETC-3018 S, ETC-3018 L, ETC-3024 S, ETC-3024 L, ETC-3024 S-X, ETC-3024 L-X], and Type IV [ETC-4018 S, ETC-4018 L, ETC-4024 S, ETC-4024 L, ETC-4024 S-X, ETC-4024 L-X])

Indications for Use *(Describe)*
Daylily Single Use Sterile Embryo Transfer Catheters are used to place in vitro fertilized (IVF) embryos into the uterine cavity.

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 – K220010

I. SUBMITTER

Applicant: Shanghai Horizon Medical Technology Co., Ltd.
Applicant Address: Room 401, building 24, No. 1-28, 588 Tianxiong Rd, Pudong New Area, Shanghai, P.R.China. Postcode: 201318.

Phone: +86-21-38954600
Fax: +86-21-50801305
Email: BeiBei.Xing@microport.com
Contact Person: Beibei Xing

Date Prepared: December 14, 2022

II. DEVICE

Trade Name: Daylily Single Use Sterile Embryo Transfer Catheters (Type I [ETC-1018 S, ETC-1018 L, ETC-1024 S, ETC-1024 L], Type II [ETC-2018 S, ETC-2018 L, ETC-2024 S, ETC-2024 L], Type III [ETC-3018 S, ETC-3018 L, ETC-3024 S, ETC-3024 L, ETC-3024 S-X, ETC-3024 L-X], and Type IV [ETC-4018 S, ETC-4018 L, ETC-4024 S, ETC-4024 L, ETC-4024 S-X, ETC-4024 L-X])
Common Name: Embryo Transfer Catheters
Regulation Name: Assisted Reproduction Catheters
Regulation Number: 21 CFR 884.6110
Regulatory Class: II
Product Code: MQF (Catheter, Assisted Reproduction)

III. PREDICATE DEVICE

Guardia™ Access Nano and Soft-Trans Embryo Transfer Catheter Sets (K172051) manufactured by Cook Incorporated.

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

IV. DEVICE DESCRIPTION

Daylily Single Use Sterile Embryo Transfer Catheters are sterile single use catheters used to deliver in vitro fertilized embryos to the uterine cavity. All models of the Daylily Single Use Sterile Embryo Transfer Catheters consist of a transfer catheter and a guide

catheter. Some device models (Type II and Type IV) also include a trial catheter.

The guide catheter is composed of a catheter shaft, connector, and a positioning ring (for certain Type III and IV variants). Guide catheters for some Type III and Type IV variants are also provided pre-curved. Guide catheters have a rounded/blunt tip and marker bands at the distal tip to aid in catheter placement. The guide catheter is delivered through the cervix first and is used to guide the insertion of the transfer catheter holding the embryos into the uterine cavity.

The transfer catheter is composed of a catheter shaft, connector, and a stainless-steel sleeve (for Type III and IV models). Transfer catheters have a rounded/blunt tip and marker bands at the proximal end of the catheter to aid in catheter placement. The transfer catheter is loaded with embryos prior to delivery through the guide catheter and into the uterine cavity. A syringe (not provided with catheters) connected to the connector of the transfer catheter is used to deliver the embryos into the uterine cavity.

The trial catheter is an optional accessory for specific models (Types II and IV), composed of a catheter shaft, connector, and a polymer-coated stainless-steel core. Trial catheters have a rounded/blunt closed tip. The trial catheter is used to provide additional support during guide catheter placement and to assess the placement of the device prior to conducting an actual embryo transfer procedure.

Device configurations and specifications for the Daylily Single Use Sterile Embryo Transfer Catheters (Types I-IV) are shown below:

Table 1. Device configurations and models

<table>
<tr><td rowspan="3">Model</td><td colspan="6">Components</td></tr>
<tr><td colspan="2">Transfer catheter</td><td colspan="2">Guide catheter</td><td colspan="2">Trial catheter</td></tr>
<tr><td>Outer Diameter (mm)/Inner Diameter (mm)</td><td>Length (cm)</td><td>Outer Diameter (mm)/Inner Diameter(mm)</td><td>Length (cm)</td><td>Outer Diameter (mm)</td><td>Length (cm)</td></tr>
<tr><td>Type I</td><td rowspan="4">0.95-1.50 mm OD/0.55-0.75 mm ID</td><td rowspan="4">18-24 cm</td><td>2.35 mm OD/1.55-1.75 mm ID</td><td rowspan="4">12-17.3 cm</td><td>N/A</td><td>N/A</td></tr>
<tr><td>Type II</td><td>1.40 mm</td><td>15.3-20.6 cm</td></tr>
<tr><td>Type III</td><td rowspan="2">2.35-2.50/ 1.55-1.90 ID</td><td>N/A</td><td>N/A</td></tr>
<tr><td>Type IV</td><td>1.40 mm</td><td>15.3-20.6 cm</td></tr>
</table>

The Daylily Single Use Sterile Embryo Transfer Catheters are intended for single use only and sterilized by ethylene oxide. They have a three-year shelf life.

V. INDICATIONS FOR USE

Daylily Single Use Sterile Embryo Transfer Catheters are used to place in vitro fertilized (IVF) embryos into the uterine cavity.

VI. COMPARISON OF THE INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT AND PREDICATE DEVICES

The following table compares the Daylily Single Use Sterile Embryo Transfer Catheters to the predicate device.

Table 2. Intended use and technological characteristics comparison.

Comparison Item	**Subject Device – K220010**	**Predicate Device – K172051**	**Comparison**
Manufacturer	Shanghai Horizon Medical Technology Co., Ltd.	Cook Incorporated	Not applicable
Trade name	Daylily Single Use Sterile Embryo Transfer Catheters (Type I [ETC-1018 S, ETC-1018 L, ETC-1024 S, ETC-1024 L], Type II [ETC-2018 S, ETC-2018 L, ETC-2024 S, ETC-2024 L], Type III [ETC-3018 S, ETC-3018 L, ETC-3024 S, ETC-3024 L, ETC-3024 S-X, ETC-3024 L-X], and Type IV [ETC-4018 S, ETC-4018 L, ETC-4024 S, ETC-4024 L, ETC-4024 S-X, ETC-4024 L-X])	Guardia™ Access Nano and Soft-Trans Embryo Transfer Catheter Sets	Not applicable
Indications for Use	Daylily Single Use Sterile Embryo Transfer Catheters are used to place in vitro fertilized	Used to place in vitro fertilized (IVF) embryos into the uterine cavity.	Same

Comparison Item		Subject Device – K220010	Predicate Device – K172051	Comparison
		(IVF) embryos into the uterine cavity.		
Dimension	Transfer catheter	OD 0.95-1.5 mm (2.85-4.5 Fr) Length 18-24 cm	OD 2.8-4.7 Fr Length 19.1-24 cm	Different
	Guide catheter	OD 2.35-2.5 mm (7.05-7.5 Fr) Length 12-17.3 cm	OD 5.5-8.1 Fr Length 11.4-17.3 cm	Different
	Trial catheter	OD 1.4mm (4.2 Fr) Length 15.3-20.6 cm	OD 4.0 Fr Length 18 cm	Different
Material	Transfer catheter	Polyurethane, polycarbonate, stainless steel (with applicable variants)	polyurethane, stainless steel	Different
	Guide catheter	Polyether block polyamide, silicone (with applicable variants)	Polyethylene, polymethylpentene, silicone	Different
	Trial catheter	Polyether block polyamide, stainless steel	Polycarbonate, stainless steel, polyurethane	Different
Variants with pre-curved guide catheter		Yes	Yes	Same
Variants with positioning rings/markers		Yes	Yes	Same
Depth markers on catheters		Yes	Yes	Same
Sterility		Sterilized by ethylene oxide	Sterilized by ethylene oxide	Same
Single Use		Yes	Yes	Same
Shelf Life		3 years	3 years	Same
Mouse Embryo Assay		1-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours.	1-cell MEA ≥80% embryos developed to blastocyst in 96 hours.	Similar
Endotoxin		< 20 EU/device	< 20 EU/device	Same

The subject and predicate devices have identical indications for use statements and the same intended use. As shown in the table above, the subject and predicate device have many technological characteristics that are the same or similar. However, there are differences in dimensions and device materials. These differences do not raise

different questions of safety and effectiveness.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE DATA

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

- Sterilization Validation testing per:
  - ISO 11135-1:2014
  - AAMI TIR 28:2016
  - ISO 10993-7: 2008
- Package Integrity testing:
  - Visual inspection
  - Bubble Leak test per ASTM F2096-11
  - Seal Strength testing per ASTM F88/ F88M-15
  - Dye Penetration test per ASTM F1929-15
- Transportation Simulation testing per ASTM D4169-14
- Biocompatibility studies conducted in accordance with the 2020 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 assessments:
  - Cytotoxicity per ISO 10993-5: 2009
  - Sensitization ISO 10993-10: 2010
  - Irritation per ISO 10993-10: 2010

  Testing showed the device material to be non-cytotoxic, non-sensitizing, and non-irritating.
- Endotoxin testing per USP <85> and AAMI/ANSI ST72:2019 - Specification: <20 EU/device
- Bench performance studies before and after accelerated aging to the equivalent of three-years of real-time aging in accordance with ASTM F1980-16 demonstrated that all predetermined acceptance criteria were met in the following tests:
  - Appearance
  - Taper/Syringe compatibility
  - Dimensional analysis
  - Distance indication marker location and durability
  - Dislodgement of positioning ring
  - Tip drop when held horizontally
  - Bonding strength of device connections/bonds
  - Aspiration and leakage testing
  - Mouse Embryo Assay (MEA) per the 2021 FDA guidance *Mouse Embryo Assay for Assisted Reproduction Technology Devices:* Specification - 1-Cell

MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours.

VIII. CONCLUSIONS

The results of the testing described above demonstrate that the Daylily Single Use Sterile Embryo Transfer Catheters are as safe and effective as the predicate device and supports a determination of substantial equivalence.