August 16, 2024

Shenzhen VitaVitro Biotech Co., Ltd.
Donghai Pan
Official Correspondent
R601, Building B, Hai Ke Xing Tech Park, Baoshan Road No.16,
Shenzhen, Guangdong 518118
China

Re: K240307
Trade/Device Name: VitaVitro Embryo Transfer Catheter (Models ET-S, ET-SI, ET-A, ET-I, ET-IH)
Regulation Number: 21 CFR§ 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: II
Product Code: MQF
Dated: July 16, 2024
Received: July 16, 2024

Dear Donghai Pan:

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)*
K240307

Device Name
VitaVitro Embryo Transfer Catheter (Models ET-S, ET-SI, ET-A, ET-I, ET-IH)

Indications for Use *(Describe)*
VitaVitro Embryo Transfer Catheter is 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 – K240307

I. SUBMITTER

Applicant:	Shenzhen VitaVitro Biotech Co., Ltd.
Applicant Address:	R601, Building B, Hai Ke Xing Tech Park Baoshan Road No. 16 Shenzhen 518118 Guangdong, China.
Phone:	86-755-84511813
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Email:	pandh@vitavitro.com
Contact Person:	Mr. Donghai Pan, International Regulatory Specialist

Date Prepared: August 14, 2024

II. DEVICE

Trade Name:	VitaVitro Embryo Transfer Catheter (Models ET-S, ET-SI, ET-A, ET-I, ET-IH)
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

Emtrac; Delphin; Semtrac 2000 Set (K013536) manufactured by Gynetics Medical Products Nv.

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

IV. DEVICE DESCRIPTION

The VitaVitro Embryo Transfer Catheters are sterile (ethylene oxide), single use catheters used to deliver in vitro fertilized embryos to the uterine cavity. They have a three-year shelf-life.

The device includes five catheter models that are composed of a transfer catheter and a guide catheter (some with obturator).

The 172 mm length Guide catheters have OD 2.4 mm for straight (Models ET-SI and ET-S) and OD 2.2 mm for the curved version type (Model ET-A).

The curved version type (Model ET-A) has an additional adjustable positioner which aids in

positioning the device to the targeted depth within the uterine cavity during a procedure. Both types 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 240 mm transfer catheter with an OD 0.95 mm is loaded with embryos prior to delivery through the guide catheter and into the uterine cavity. A syringe (not provided with catheters) is connected to the connector of the transfer catheter and is used to deliver the embryos into the uterine cavity.

The 200 mm obturator with OD 1.3 mm is an optional accessory for the device. It has a rounded/blunt closed tip. The obturator is used to provide additional support (increase rigidity) during guide catheter placement and to assess the placement of the device prior to conducting an actual embryo transfer procedure.

V. INDICATIONS FOR USE

VitaVitro Embryo Transfer Catheter is 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 VitaVitro Embryo Transfer Catheters to the predicate device.

Table 3. Intended use and technological characteristics comparison.

Comparison Item	**Subject Device K240307 ET-S, ET-SI, ET-A, ET-I, ET-IH**	**Predicate Device K013536 EMTRAC; DELPHIN; SEMTRAC 2000 SET**	**Comparison**
Company/Sponsor	Shenzhen VitaVitro Biotech Co., Ltd	Gynetics Medical Products Nv	NA
Regulation	884.6110	884.6110	Same
Product Code	MQF	MQF	Same
Indications for Use	VitaVitro Embryo Transfer Catheter is used to place in vitro fertilized (IVF) embryos into the uterine cavity.	The delphin is to be used for embryo transfer and intra uterine insemination procedures for in vitro fertilization (ivf) and related assisted reproduction technology (art) procedures.	The indications for use for the subject and predicate devices are not identical; however, they have the

		Emtrac catheters are to be used for embryo transfer procedures for in vitro fertilization (ivf) and related assisted reproduction technology (art) procedures. Semtrac sets are to be used for embryo transfer procedures for in vitro fertilization (ivf) and related assisted reproduction technology (art) procedures.	same intended use (i.e., transfer of embryos to the uterine cavity).
Design Features	Transfer catheter: With insertion depth scale, stainless steel core tube, and Luer lock hub Guide: Straight or curved with positioner (Model ET-A only), with insertion depth scale, and Leur lock hub. Obturator	Inner catheter (loading catheter), luer lock hub, outer tube (guiding catheter), positioner for depth adjustment, obturator (mandrel)	**Different** The differences in design features identified do not raise different questions of safety and effectiveness (S&E)
Material	Transfer Catheter - TPU, stainless steel, ABS, depth marker ink Guide – TPU-LDPE, ABS (straight guide catheter) or PEBAX, nylon, silicone (curved guide catheter), depth marker ink Obturator – PP, stainless steel, ABS	Positioner and handle: polyethylene (PP) Transfer catheter: polyethylene (PE) Guide- Polypropylene Stylet: stainless steel	**Different** The differences in device materials do not raise different questions of S&E.

Dimension	Length: Transfer catheter – 240 mm Guide catheter – 172 mm Obturator-200 mm O.D.: Transfer catheter – 0.95 mm Guide catheter – 2.4 mm (straight), 2.2 mm (curved) Obturator-1.3 mm	Length: Transfer catheter: 266 mm Guide catheter: 216 mm Obturator: 240 mm Tube O.D.: Guide catheter – 1.60 mm Transfer catheter –1.00 mm Obturator- 1.00 mm	**Different** The differences in device dimensions do not raise different questions of S&E.
Sterility	Sterilized by ethylene oxide exposure	Sterilized by Gamma irradiation	**Different** The differences in device sterilization methods do not raise different questions of S&E.
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 96h	1-Cell MEA: ≥ 80% embryos developed to blastocyst at 96h	Similar
Endotoxin	< 5 EU/device	< 20 EU/device	**Different** The differences in endotoxin specifications do not raise different questions of S&E.

The subject and predicate devices have differences in their indications for use statements; however, their intended uses are the same (i.e., transfer of embryos to the uterine cavity). As

shown in the table above, there are differences in technological characteristics between the subject and predicate devices. However, as stated in the table, 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:
  - ISO 11135-1:2014
  - ISO 10993-7: 2008

- Package integrity testing:
  - Visual inspection per ASTM F1886/F1886M-16
  - Seal Strength testing per ASTM F88/ F88M-15
  - Dye Penetration test per ASTM F1929-15

- Transportation Simulation testing per ASTM D4169-22

- Biocompatibility studies conducted 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 assessments:

  - Cytotoxicity per ISO 10993-5: 2009
  - Sensitization ISO 10993-10: 2021
  - Irritation per ISO 10993-23: 2021

  Testing showed the device material to be non-cytotoxic, non-sensitizing, and non-irritating.

- Endotoxin testing per USP <85> Specification: <5 EU/device

- 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.

- Bench performance studies before and after accelerated aging to the equivalent of three-years of real-time aging in accordance with ASTM F1980-21 demonstrated that all predetermined acceptance criteria were met in the following tests:
  - Appearance
  - Taper/Syringe compatibility
  - Transfer catheter and obturator compatibility with guide catheter
  - 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 of transfer catheter
- Corrosion resistance of stainless steel tube
- Tensile/bonding strength test to assess all joints
- Flow rate of transfer catheter

VIII. CONCLUSIONS

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