November 15, 2024

Donghai Pan
Official Applicant
R601, Building B, Hai Ke Xing Tech Park
Baoshan Road No. 16
Shenzhen, Guangdong 518118
CHINA

Re: K240523
Trade/Device Name: VitaVitro® Single Lumen Oocyte Retrieval Needle (ORNS-17G, ORNS-18G);
VitaVitro® Double Lumen Oocyte Retrieval Needle (ORND-17G)
Regulation Number: 21 CFR 884.6100
Regulation Name: Assisted Reproduction Needles
Regulatory Class: II
Product Code: MQE
Received: October 15, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Monica D. Garcia -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240523

Device Name

VitaVitro® Single Lumen Oocyte Retrieval Needle (ORNS-17G, ORNS-18G)
VitaVitro® Double Lumen Oocyte Retrieval Needle (ORND-17G)

Indications for Use *(Describe)*

VitaVitro Single Lumen Oocyte Retrieval Needle is intended for ultrasound guided transvaginal aspiration of oocytes from ovarian follicles for patients undergoing Assisted Reproductive procedures.

VitaVitro Double Lumen Oocyte Retrieval Needle is intended 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 – K240523

1. Submission Sponsor

Shenzhen VitaVitro Biotech Co., Ltd.
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Email: pandh@vitavitro.com

2. Date Prepared

November 14, 2024

3. Device Identification

Trade/Device Name:	VitaVitro® Single Lumen Oocyte Retrieval Needle (ORNS-17G, ORNS-18G); VitaVitro® Double Lumen Oocyte Retrieval Needle (ORND-17G)
Common Name:	Oocyte Retrieval Needle
Regulation Number:	21 CFR § 884.6100
Regulation Name:	Assisted Reproduction Needles
Device Classification:	Class II
Product Code:	MQE (Needle, Assisted Reproduction)

4. Predicate Device

Predicate Device	**Trade Name**	Ovum Pick-Up Aspiration Needle
	Manufacturer	Cook OB/GYN
	510(k) No.	K983593
	Regulatory Class	Class II
	Product Code	MQE

The predicate device has not been subject to any design-related recalls.

5. Device Description

The Oocyte Retrieval Needle is composed of a stainless steel needle, needle protective sleeve, needle handle, suction catheter, silicone plug, vacuum catheter, flushing catheter and taper joint. The device includes both dual lumen (ORND) and single-lumen needles (ORNS). Three models are available: ORNS-17G, ORNS-18G and ORND-17G. The oocyte retrieval needles are available in 17 or 18 gauge sizes and two lengths: 33 and 35 cm. The needles are provided with a suction catheter of 100 cm length and a vacuum

catheter with a length of 35 cm, and the ORND-17G also includes a flushing catheter of 100 cm length. Needles have an echogenic tip that enhances the visualization of the needle tip under ultrasound.

This product is a disposable, sterile medical device, sterilized by ethylene oxide.

6. Indications For Use

VitaVitro Single Lumen Oocyte Retrieval Needle is intended for ultrasound guided transvaginal aspiration of oocytes from ovarian follicles for patients undergoing Assisted Reproductive procedures.

VitaVitro Double Lumen Oocyte Retrieval Needle is intended for ultrasound guided transvaginal aspiration and flushing of oocytes from ovarian follicles for patients undergoing Assisted Reproductive procedures.

7. Substantial Equivalence Discussion

The tables below list the comparisons of the indications for use and technological characteristics of the subject and predicate devices.

Parameter	Subject Device	Predicate Device	Comparison
Indications for Use	VitaVitro Single Lumen Oocyte Retrieval Needle is intended for ultrasound guided transvaginal aspiration of oocytes from ovarian follicles for patients undergoing Assisted Reproductive procedures. VitaVitro Double Lumen Oocyte Retrieval Needle is intended for ultrasound guided transvaginal aspiration and flushing of oocytes from ovarian follicles for patients undergoing Assisted Reproductive procedures.	The Ovum Pick-Up Aspiration Needles used for aspiration and flushing of oocytes from ovarian follicles.	**Different:** The indications for use for the subject device and predicate device are not identical; however, they have the same intended use (i.e. aspiration or/and flushing of oocytes from ovarian follicles)
Design Features	needle, needle protective sleeve, needle handle, aspiration catheter, silicone plug, vacuum catheter, flushing catheter and taper joint.	needle, aspiration line, plug, with or without vacuum line, flushing line and taper joint.	**Different**
Dimension	ORNS-17G, ORNS-18G: Needle: 33 cm Aspiration catheter:100 cm Vacuum catheter:35 cm Needle Gauge: 17G or 18G ORND-17G Needle: 35 cm Aspiration catheter:100 cm Vacuum catheter:35 cm Flushing catheter:100 cm Needle Gauge: 17G	G44360, G55248, G55252: Needle length:30 cm or 35 cm Aspiration line: 60 cm,90 cm Needle gauge:16G or 17G Vacuum line: Not available G55796, G55798: Needle Gauge: 16G or 17G Needle Length: 35 cm Aspiration Tubing: 75 cm Flushing Tubing: 70 or 100 cm Vacuum line: Not available	**Different**

Parameter	Subject Device	Predicate Device	Comparison
Device Materials	Stainless steel, TPU, silicone PE	Stainless steel, Tetrafluoroethylene (NRT[TFE])	**Different**
Needle type	Single Lumen Ovum Aspiration Needles and Double Lumen Ovum Aspiration Needles	Single Lumen Ovum Aspiration Needles and Double Lumen Ovum Aspiration Needles	Same
Endotoxin	< 5EU/device	Not publicly available	Different
MEA	≥80% embryos developed to expanded blastocyst at 96h	Not publicly available	Different
Sterile	No microbial growth	No microbial growth	Same
Single Use	Yes	Yes	Same
Shelf life	2 years	Not publicly available	Different

The subject and predicate device have the same intended use – to transvaginally aspirate oocytes from ovarian follicles with the aid of ultrasound imaging. In addition, as shown in the table above, there are technological differences between the subject and predicate device, including the device components, device dimensions, materials used, performance testing, and shelf-life. However, these differences do not raise different questions of safety and effectiveness.

8. Summary of Non-Clinical Performance

The following studies have been performed for the device to support the substantial equivalence to the predicate device 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."*

- Biocompatibility evaluation
  - Cytotoxicity (ISO 10993-5:2009)
  - Sensitization (ISO 10993-10:2021)
  - Irritation (ISO 10993-23:2021)

  Testing results demonstrate that the subject devices are non-cytotoxic, non-irritating, and non-

sensitizing.

- 1-cell MEA per the 2021 FDA guidance document *Mouse Embryo Assay for Assisted Reproduction Technology Devices*: ≥80% embryos developed to expanded blastocyst at 96h
- Endotoxin testing: < 5EU/device, LAL testing by Gel Clot assay per USP<85>
- Sterility testing
  - Sterile, ethylene oxide, SAL of 10^{-6} (ISO 11135:2014)
  - Residual testing (ISO 10993-7:2008)
- Shipping and package integrity testing
  - Simulated shipping per ASTM D 4169:2016 DC13
  - Package integrity per ASTM F88/F88M:2021 (seal peel strength), ASTM F1929:2015 (dye penetration)
- Mechanical performance testing
  - Appearance per ISO 7864:2016
  - Dimensional verification
  - Hydraulic resistance per ISO 20695:2020, Annex D
  - Vacuum leakage
  - Tensile strength test per ISO 20695:2020, Annex C
  - Flow rate per ISO 20695:2020, Annex E
  - Puncture needle test per ISO 9626:2016, Annex B-D: Rigidity test, Toughness test, Corrosion resistance
  - Needle penetration force per ISO 7864:2016, Annex D
  - Ultrasound detectability test
  - Collection tube compatibility test
- Shelf-life testing was conducted to ensure that product specifications for endotoxin, MEA, sterility, and package integrity were met over the proposed shelf-life period.

9. 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.