October 16, 2020

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

Re: K200408
Trade/Device Name: VitaVitro® Fertilization Medium,
VitaVitro® Gamete Buffer Medium,
VitaVitro® Flushing Buffer Medium
Regulation Number: 21 CFR § 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: September 4, 2020
Received: September 14, 2020

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 (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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200408

Device Name

VitaVitro® Fertilization Medium, VitaVitro® Gamete Buffer Medium, VitaVitro® Flushing Buffer Medium

Indications for Use *(Describe)*

VitaVitro® Fertilization Medium is intended for preparation and handling of human gametes and for in vitro fertilization.

VitaVitro® Gamete Buffer Medium is intended for human gamete and embryo short-term handling procedures outside the incubator, including washing and intracytoplasmic sperm injection (ICSI).

VitaVitro® Flushing Buffer Medium is intended for use during ovarian follicle flushing and oocyte collection procedures for use in in vitro fertilization 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.

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510(k) Summary
K200408

1. Submission Sponsor

Shenzhen VitaVitro Biotech Co., Ltd.
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2. Date Prepared

October 15, 2020

3. Device Identification

Trade/Device Name:	VitaVitro® Fertilization Medium, VitaVitro® Gamete Buffer Medium, VitaVitro® Flushing Buffer Medium
Common Name:	Assisted Reproduction Medium
Regulation Number:	21 CFR 884.6180
Regulation Name:	Reproductive Media and Supplements
Device Classification:	Class II
Product Code:	MQL (Media, Reproductive)

4. Predicate Device

Subject Device		VitaVitro® Fertilization Medium	VitaVitro® Gamete Buffer Medium	VitaVitro® Flushing Buffer Medium
Predicate Device	**Name**	Global® Total® for Fertilization w/ HSA	Quinn's HTF Medium with HEPES	Sydney IVF Follicle Flush Buffer
	Manufacturer	Lifeglobal Group, LLC	Advanced Reproductive Technologies	William A. Cook Australia Pty Ltd
	510(k) No.	K142991	K991395	K153290

The predicate devices have not been subjected to any design related recalls.

5. DEVICE DESCRIPTION

This submission includes three media products:

- VitaVitro® Fertilization Medium is intended for preparation and handling of human gametes and for in vitro fertilization. Media provided in volumes of 30 ml and 60 ml.
- VitaVitro® Gamete Buffer Medium intended for human gamete and embryo short-term handling procedures outside the incubator, including washing and intracytoplasmic sperm injection (ICSI). Media provided in a

single volume of 60 ml.

- VitaVitro® Flushing Buffer Medium intended for use during in vitro fertilization procedures for follicle flushing and oocyte collection. Media provided in volumes of 60 ml and 125 ml.

All devices are aseptically filled into radiation-sterilized PETG bottles, are single-use only, and have a shelf-life of six-months when stored as recommended at 2-8°C. Additional information on the formulation of the subject devices is provided in Section 7 of this summary.

6. INDICATIONS FOR USE:

The subject device Indications for Use statements (IFU) are shown below:

No.	Device Name	INDICATIONS FOR USE
1	VitaVitro® Fertilization Medium	VitaVitro® Fertilization Medium is intended for preparation and handling of human gametes and for in vitro fertilization.
2	VitaVitro® Gamete Buffer Medium	VitaVitro® Gamete Buffer Medium is intended for human gamete and embryo short-term handling procedures outside the incubator, including washing and intracytoplasmic sperm injection (ICSI).
3	VitaVitro® Flushing Buffer Medium	VitaVitro® Flushing Buffer Medium is intended for use during ovarian follicle flushing and oocyte collection procedures for use in in vitro fertilization procedures.

A comparison of the subject and predicate device intended use is shown below:

Subject Device IFU statement	Predicate Device IFU Statement	Intended Use Comparison
VitaVitro® Fertilization Medium is intended for preparation and handling of human gametes and for in vitro fertilization.	Global Total Fertilization with HSA: Oocyte culture and fertilization	The IFU statement wording is different but the intended use is the same i.e. (handling of human gametes and in vitro fertilization).
VitaVitro® Gamete Buffer Medium is intended for human gamete and embryo short-term handling procedures outside the incubator, including washing and intracytoplasmic sperm injection (ICSI).	Quinn's HTF medium with HEPES was developed for in vitro procedures involving manipulations of gametes and embryos not requiring the use of a CO_2 incubator. Such procedures include oocyte recovery, gamete washing, micromanipulation, embryo transfer and cryopreservation.	The intended use of the subject and predicate device is the same regarding short-term handling procedures of human gametes and embryo outside of an incubator. However, the predicate device has additional uses beyond that of the subject device (embryo transfer and cryopreservation). These differences do not represent a new intended use, but rather a more limited intended use for the subject device.
VitaVitro® Flushing Buffer Medium is intended for use during ovarian follicle flushing and oocyte collection procedures for use in in vitro fertilization	Sydney IVF Follicle Flush Buffer is intended for use during in vitro fertilization procedures for follicle flushing and oocyte collection.	The intended use of the predicate and subject device is the same (follicle flushing and oocyte collection).

procedures.		

7. Substantial Equivalence Discussion

A comparison of the technological features of the subject and predicate device are described in the table below:

Device & Predicate Device(s):	**K200408 VitaVitro® Fertilization Medium, VitaVitro® Gamete Buffer Medium, and VitaVitro® Flushing Buffer Medium**	**K142991 Global Total Fertilization with HSA (predicate for VitaVitro® Fertilization Medium)**	**K991395 Quinn's HTF Medium with HEPES (predicate for VitaVitro® Gamete Buffer Medium)**	**K153290 Sydney IVF follicle flush buffer (predicate for VitaVitro® Flushing Buffer Medium)**	**Comments**
Formulation	Glucose Sodium Lactate Sodium Pyruvate HEPES* HEPES Sodium* Sodium Bicarbonate Sodium Chloride Potassium Chloride Potassium Phosphate Magnesium Sulphate Calcium Chloride Amino acids Taurine Sodium Citrate EDTA Phenol red Gentamicin sulfate HSA**	Sodium Chloride Calcium chloride Potassium Phosphorus Magnesium Sulfate Sodium Bicarbonate Glucose Sodium Lactate Sodium Pyruvate Amino acids Glycine glutamine EDTA Phenol red Gentamicin sulfate HSA Water	Not known	D-Glucose Gentamicin Calcium -Lactate Glutamine Glycine L-alanine L-asparagine L-aspartic acid L-glutamic acid L-proline L-serine Magnesium sulphate Potassium chloride Potassium phosphate Purified water Sodium bicarbonate Sodium chloride Sodium pyruvate Taurine	**Different:** The materials in the formulations of the subject and their respective predicate devices are not identical or is not known (i.e., predicate for VitaVitro® Gamete Buffer Medium). These differences do not raise different questions of Safety and Effectiveness (S&E).

Packaging	30 and 60 ml PETG square bottle – Fertilization Medium 60 ml PETG square bottle – Gamete Buffer Medium 60 and 125 ml PETG square bottle – Flushing Buffer Medium	50 and 100 ml	Not known	20, 50, and 100 ml borosilicate Type 1 glass vial with Fluorotec coated rubber stopper	**Different**: Bottle sizes between the subject devices and their respective predicates are not the same or are not known (i.e., predicate for VitaVitro® Gamete Buffer Medium). Differences in packaging do not raise different questions of S&E.
Shelf-life	6 months	10 weeks	Not known	20 weeks	**Different:** Shelf-life of the subject devices and their respective predicates are not the same or is not known (i.e., predicate for VitaVitro® Gamete Buffer Medium). Differences in shelf-life do not raise different questions of S&E.
pH	7.2-7.6	7.2-7.4	Not known	7.37.50	**Different**. The subject devices pH range is greater than their respective predicate devices (i.e., 7.6) or is not known (i.e., predicate for VitaVitro® Gamete Buffer Medium). Differences in pH do not raise different questions of S&E.
Osmolality	260-290	260-270	Not known	285-295	**Different.** The subject devices osmolality specifications are different than their respective predicate devices or is not known

					(i.e., predicate for VitaVitro® Gamete Buffer Medium). Differences in osmolality do not raise different questions of S&E.
Endotoxin	<0.25	<0.5 EU/ml	Not Known	<0.40 EU/Ml	**Different:** The endotoxin specifications for the subject devices is lower than their respective predicates or is not known (i.e., predicate for VitaVitro® Gamete Buffer Medium). Differences in endotoxin specifications do not raise different questions of S & E.
MEA	1-cell MEA: ≥80% expanded blastocyst at 96 hours after a 24-hour exposure to media (Fertilization media). 1-cell MEA: ≥80% expanded blastocyst at 96 hours after a 2-hour exposure to media (Gamete Buffer Medium and Flushing Buffer Medium).	1-cell MEA≥80% blastocysts at 96 h of culture	Not Known	>80% 2-Cell MEA	**Different:** The MEA specifications for the subject devices (e.g., embryo type, exposure to test media, etc.) is different than their respective predicates or is not known (i.e., predicate for VitaVitro® Gamete Buffer Medium). Differences in MEA specifications do not raise different questions of S & E.
Sterility	No growth	SAL 10^{-3}	Not known	Aseptically filtered	**Different:** The sterility specification is different than its respective predicate devices or is not known ((i.e., predicate for VitaVitro® Gamete Buffer Medium). This difference does not raise different questions of

					S&E.

*not included in Fertilization Medium

**not included in Flushing Buffer Medium

The technological characteristics of the subject devices and their respective predicate devices are not the same as stated in the table above (e.g., formulation, packaging, shelf-life, device specifications, etc.). However, the differences in technological characteristics do not raise different questions of safety and effectiveness as compared to their respective predicate devices.

8. Summary of Non-Clinical Performance

VitaVitro® Fertilization Medium, VitaVitro® Gamete Buffer Medium, and VitaVitro® Flushing Buffer Medium underwent the following testing to assess their performance and demonstrate substantial equivalence to their respective predicate devices. The testing and specifications below, unless otherwise stated, apply to each of the subject media products:

- pH testing: 7.20 - 7.60
- Osmolality testing: 260 – 290 mOsm/kg
- Endotoxin (per USP<85>): <0.25 EU/ml
- MEA;
  - 1-cell MEA: ≥80% expanded blastocyst at 96 hours after a 24-hour exposure to media (Fertilization media).
  - 1-cell MEA: ≥80% expanded blastocyst at 96 hours after a 2-hour exposure to media (Gamete Buffer Medium and Flushing Buffer Medium).
- Sterility Testing (per USP <71>): No growth
- Shelf-life testing was conducted at time 0 and after accelerated aging (equivalent to six months of real-time aging) to ensure the product specifications listed above were met.
- Transportation testing per ASTM D4169-2016 (Standard Practice for Performance Testing of Shipping Containers and Systems)
- Sterilization validation was conducted in accordance with ISO 13408-1: 2015 (Aseptic processing of health care products - Part 1: General requirements) and ISO 13408-2: 2018 (Aseptic processing of health care products - Part 2: Sterilizing filtration).
- Biocompatibility testing was conducted on VitaVitro® Flushing Buffer Medium as this device will have direct contact with the patient during use. Testing was 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:

  - Cytotoxicity per ISO 10993-5: 2009
  - Sensitization per ISO 10993-10: 2010
  - Irritation per ISO 10993-10: 2010

  The testing demonstrated that VitaVitro® Flushing Buffer Medium is non-cytotoxic, non-sensitizing, and non-irritating.

9. Conclusion

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