August 23, 2019

Shenzhen VitaVitro Biotech Co., Ltd.
Xiaozhen Lin, CEO
R601, Building B, Hai Ke Xing Tech Park
Baoshan Road No.16
Shenzhen 518118 Guangdong
CHINA

Re: K191063
Trade/Device Name: 1-Step Culture Medium
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: Class II
Product Code: MQL
Dated: July 22, 2019
Received: July 24, 2019

Dear Xiaozhen Lin:

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,

Sharon M. Andrews
Assistant Division 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)*
K191063

Device Name

1-Step Culture Medium

Indications for Use *(Describe)*

This product is intended for the in vitro culture of human embryos following fertilization until Day 5/6 of development.

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 – K191063

1. Submission Sponsor

Shenzhen VitaVitro Biotech Co.,Ltd.
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Shenzhen, Guangdong, 518118, P. R. China
Contact person: Ms. Xiaozhen Lin, CEO
Telephone: 86-755-84511813
Fax: 86-755-85235226
Email: jenny@vitavitro.com

3. Date Prepared

August 23, 2019

4. Device Identification

Device Name: 1-Step Culture Medium
Common Name: Embryo Culture Medium
Regulation Name: Reproductive media and supplements
Regulation Number: 21 CFR § 884.6180
Device Classification: Class II
Product Code: MQL (Media, Reproductive)

5. Predicate Device

G-TL™ IVF Media (K133568), manufactured by Vitrolife, Inc.
The predicate device has not been subject to any design related recalls.

6. DEVICE DESCRIPTION

VitaVitro® 1-Step Culture Medium is a one-step media product intended for the in vitro culture of embryos from fertilization until day 5/6 of development. It is an aseptically filtered, bicarbonate-buffered media containing physiological salt solutions, gentamicin, and human serum albumin. It is ready to use after warming to 37°C and equilibration in a CO_2 environment.

Specifications for the 1-Step Culture Medium are listed in the table below:

Aspect	Specification
Sterility (per USP <71>)	No microbial growth
Osmolality	250 – 290 mOsm/kg

pH	7.2 – 7.6
Endotoxin (per USP <85>)	<0.25 EU/ml
1-cell MEA	≥80% developed to the blastocyst stage within 96 hours

7. INDICATIONS FOR USE:

This product is intended for the in vitro culture of human embryos following fertilization until Day 5/6 of development.

8. Substantial Equivalence Discussion

A comparison of the subject device and the predicate device is shown in the table below.

Device	Subject Device (K191063)	Predicate Device (K133568)
Indications for Use	This product is intended for the in vitro culture of human embryos following fertilization until Day 5/6 of development.	G-TL™ is a medium for culture of embryos from fertilization to blastocyst stage.
pH	7.20 - 7.60	7.2 – 7.4
Osmolality (mOsm/Kg)	250 – 290	265 - 275
Bacterial endotoxin (EU/ml)	<0.25	<0.25
Mouse embryo assay (% expanded blastocyst within 96 hours)	≥ 80	≥ 80
Sterility	No growth	10^{-3}
Storage conditions	Store at +2 to 8℃	Store dark at +2 to 8℃
Formulation	Physiological salts Amino acids Taurine Alanyl-glutamine Energy sources Antioxidant Buffer HSA Gentamicin sulphate Phenol Red	Physiological salts Amino acids Taurine Alanyl-glutamine Energy sources Antioxidant Buffer HSA Gentamicin sulphate Sodium hyaluronate

As shown in the table above, the subject and predicate device have similar indications for use statements and the same intended use – the culture of embryos up to day 5/6 of development (blastocyst stage). The technological characteristics of the subject and predicate device are different - the subject device has differences in formulation and different osmolality and pH specifications. However, different types of safety and effectiveness questions are not raised by these differences in technological characteristics.

9. Summary of Non-Clinical Performance Testing

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

* pH testing
* Osmolality testing
* 1-cell MEA

  One-cell mouse embryos were exposed to subject devices and cultured at 37°C in an atmosphere containing 5% CO_2. The percent of embryos developed to the expanded blastocyst stage at 96 hours were assessed in comparison with the control group.
* Endotoxin per USP <85>
* Sterility per USP <71>
* Aseptic Processing Validation per ISO 13408-1:2008 and ISO 13408-2:2018;
* Shelf-life testing was conducted to ensure that the specifications for the following product characteristics are met at time zero and the end of shelf-life (six months):
  - pH testing
  - Osmolality testing
  - 1-cell MEA
  - Endotoxin
  - Sterility

10. Conclusion

The subject and predicate devices have the same intended use and comparable technological characteristics. The differences in technological characteristics between the subject and predicate devices do not raise questions on safety and effectiveness. The performance data demonstrates that the subject device is substantially equivalent to the predicate device.