November 20, 2020

VITROMED GmbH
% Greg Holland
Consultant
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606

Re: K193285
Trade/Device Name: V-ONESTEP
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: October 19, 2020
Received: October 20, 2020

Dear Greg Holland:

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)*
K193285

Device Name
V-ONESTEP

Indications for Use *(Describe)*
V-ONESTEP 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 – K193285

510(k) Owner	VITROMED GmbH Hans-Knöell-Str. 6 07745 Jena Germany Phone: +49 36 41 5 39 19 76 Facsimile: +49 36 41 5 39 19 77
Contact person	Greg Holland Regulatory Specialists, Inc. 628 El Mirador Drive Fullerton, CA 92835 Phone: 949.262.0411 Fax: 949.552.2821 Email: greg@regulatoryspecialists.com
Date Prepared	November 18, 2020
Trade/Device Name	V-ONESTEP
Common Name	Assisted Reproduction Medium
Regulation Name	Reproductive Media and Supplements
Regulation Number	21 CFR 884.6180
Product Code	MQL (Media, Reproductive)
Class	Class II
Predicate	Shenzhen VitaVitro Biotech Co, Ltd 1-Step Culture Medium K191063

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

Description

V-ONESTEP is a medium for culturing human embryos following fertilization up to day 6 of development. The device is provided sterile-filtered into pre-sterilized 20 ml glass or 10 ml PETG bottles. V-ONESTEP has a shelf-life of 90 days when stored at 2-8°C and can be use for seven days after opening bottles. Additional information on the formulation and specifications of V-ONESTEP are provided in the Comparison of the Subject and Predicate Device Intended Use and Technological Characteristics section of this summary.

Indications for Use

V-ONESTEP is intended for the in vitro culture of human embryos following fertilization until day 5/6 of development.

Comparison of the Subject and Predicate Device Intended Use and Technological Characteristics

A comparison of the intended use and technological features of the subject and predicate devices are described in the table below:

Device & Predicate Device(s):	**K193285 V-ONESTEP Subject Device**	**K191063 1-Step Culture Medium Predicate Device**	**Comparison**
Indication for Use Statement	V-ONESTEP is intended for the in vitro culture of human embryos following fetrilization until day 5/6 of development.	This product is intended for the in vitro culture of human embryos following fertilization until Day 5/6 of development.	**Same**: The subject and predicate devices have the same indications for use and intended uses.
Formulation	Calcium lactate 5H20 NaHCO3 Sodium hyaluronate KCl NaCl MgSO4,7H2O KH2PO4 EDTA,4Na Phenol Red Sodium salt Citric acid, 3Na salt dihydrate D-Pantothenic acid calcium salt	Physiological salts Amino acids Taurine Alanyl-glutamine Energy sources Antioxidant Buffer HSA Gentamicin sulphate Phenol Red	**Different:** The materials in the subject and predicate devices are not identical. This difference does not raise different questions of Safety and Effectiveness (S&E).

	Alanyl-glutamine D(+)Glucose Sodium pyruvate Gentamicine L-Arginine hydrochloride L-Cystine L-Histidine hydrochloride-H2O L-Isoleucine L-Leucine L-Lysine hydrochloride L-Methionine L-Phenylalanine L-Threonine L-Tryptophan L-Tyrosine L-Valine L-Aspartic Acid L-Glutamic acid Glycine L-Proline L-Asparagine.H2O L-Serine Human Serum Albumin		
Shelf Life	90 days	6 months	**Different:** Shelf-life differences do not raise different questions of

			S&E
pH	7.2-7.4	7.2-7.6	**Similar**
Osmolality	257-273 mOsm/kg	250-290 mOsm/kg	**Similar**
Endotoxin	<0.25 EU/ml	< 0.25 EU/ml	**Same**
MEA	1-cell MEA: ≥80% expanded blastocyst at 120 hours	1-cell MEA: ≥80% expanded blastocysts within 96 hours	**Different:** The MEA assessment time for the subject device is longer than predicate. The longer assessment time for the subject device does not raise different questions of S&E.
Sterility	No growth	No growth	**Same**

As shown in the table above, the subject and predicate device have the same indications for use statements and the same intended use. The technological characteristics of the subject and predicate device are different as the subject device has differences in formulation, shelf-life, and MEA specification. However, these differences do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Performance
The following studies have been performed to support substantial equivalence to the predicate device:

- pH testing: 7.20 - 7.4
- Osmolality testing: 257 – 273 mOsm/kg
- Endotoxin (per USP<85>): <0.25 EU/ml
- MEA: 1-cell MEA: ≥80% expanded blastocyst at 120 hours

  One-cell mouse embryos were exposed to the subject device and cultured at 37°C in an atmosphere containing 5% CO_2. The percent of embryos developed to the expanded blastocyst stage at 120 hours were assessed in comparison with the control group.

- Sterility Testing (per Ph. Eur 2.6.1 [harmonized with USP<71>]): No growth

- Sterilization validation was conducted in accordance with ISO 13408-1:2008 (R)2011.- 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
- Shelf-life testing was conducted to ensure that device specifications for the following parameters are met at time zero and at the end of shelf-life (90 days): pH, osmolality, sterility, 1-cell MEA, and endotoxin.
- Stability testing after bottle opening was conducted to ensure that device specifications for the following parameters are met seven days after opening of bottles: pH, osmolality, sterility, 1-cell MEA, and endotoxin.
- Shipping and distribution testing to assess ability of device packaging to withstand the rigors of shipping)

Conclusions

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 different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.