September 14, 2022

Vitromed Langenfeld
c/o Greg Holland
Sr. Partner
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606

Re: K213293
Trade/Device Name: V-HEPES PLUS
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: August 15, 2022
Received: August 16, 2022

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213293

Device Name
V-HEPES PLUS

Indications for Use *(Describe)*
V-HEPES PLUS is intended for oocyte collection, intracytoplasmic sperm injection (ICSI) fertilization, and oocyte and embryo washing and handling procedures. V-HEPES PLUS is also intended for transfer of embryos to 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
K213293

510(k) Owner	VITROMED GmbH Raiffeisenstr. 15a 40764 Langenfeld Germany Ines Diener Phone: +49 2173-20041-30 Facsimile: +49 2173-20041-58
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Submission Correspondent	Greg Holland Regulatory Specialists, Inc. 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949.262.0411 Fax: 949.552.2821 Email: greg@regulatoryspecialists.com
Date Prepared	September 9, 2022
Trade Name	V-HEPES PLUS
Common Name	Assisted Reproduction Media
Regulation Name	Reproductive Media and Supplements
Regulation Number	21 CFR 884.6180
Class	Class II
Product Code	MQL (Media, Reproductive)
Predicate Device	K142991 LifeGlobal Group, LLC LifeGlobal Global Total W/HEPES W/HSA The predicate device has not been subject to a design-related recall.

Device Description

V-HEPES PLUS is a medium for oocyte collection, intracytoplasmic sperm injection (ICSI) fertilization, and oocyte and embryo washing and handling procedures. V-HEPES PLUS is also intended for transfer of embryos to the uterine cavity. The medium is aseptically filtered and provided in a volume of 100 mL in pre-sterilized PETG bottles. V-HEPES PLUS has a shelf-life of 12 months when stored at 2-8°C and can be used for up to seven days after bottle opening. Additional information on the formulation and specifications of V-HEPES PLUS are provided in the Comparison of the Subject and Predicate Device Intended Use and Technological Characteristics section of this summary.

Indications for Use

V-HEPES PLUS is intended for oocyte collection, intracytoplasmic sperm injection (ICSI) fertilization, and oocyte and embryo washing and handling procedures. V-HEPES PLUS is also intended for transfer of embryos to the uterine cavity.

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:

	K213293 V-HEPES PLUS	**K142991 LifeGlobal Global Total w/HEPES w/HSA**	**Comparison**
Indications for Use	V-HEPES PLUS is intended for oocyte collection, intracytoplasmic sperm injection (ICSI) fertilization, and oocyte and embryo washing and handling procedures. V-HEPES PLUS is also intended for transfer of embryos to the uterine cavity.	Oocyte and embryo washing, manipulation, fertilization by intracytoplasmic sperm injection (ICSI), and embryo transfer.	There are differences in the indications for use statements for the subject and predicate device, including use of the subject device for collection of aspirated oocytes; however, the intended uses of the subject and predicate devices are the same.
Conditions for Use	Prescription Use Only	Prescription Use Only	Same
Formulation	Water; Sodium Bicarbonate; Calcium Lactate; Potassium Chloride; Sodium Chloride; Magnesium Sulfate; Potassium Phosphate; EDTA; Phenol Red, Sodium; Taurine; Sodium Citrate; D-Calcium Pantothenate; Alanyl-Glutamine; Glucose; Sodium Pyruvate; Gentamicin Sulfate; L-Aspartic Acid; L-Glutamic acid; Glycine; L-Proline; L-Asparagine; L-Serine; L-Arginine Hydrochloride; L-Cystine; L-Histidine Hydrochloride; L-Isoleucine; L-Leucine; L-Lysine Hydrochloride; L-Methionine; L-Phenylalanine; L-Threonine; L-Tryptophan; L-Tyrosine; L-Valine; HEPES; Human Serum Albumin (HSA)	Sodium Chloride; Potassium Chloride; Calcium Chloride; Potassium Phosphate; Magnesium Sulfate; Sodium Bicarbonate; Glucose; Sodium Lactate; Sodium Pyruvate; L-Arginine; L-Cystine; L-Histidine; L-Isoleucine; L-Leucine; L-Lysine; L-Methionine; L-Phenylalanine; L-Threonine; L-Tryptophan; L-Tyrosine; L-Valine; L-Alanine; L-Asparagine; L-Aspartic Acid; L-Glutamic Acid; Glycine; L-Proline; L-Serine; Glycyl-L-glutamine; EDTA; Phenol Red; Gentamicin Sulfate; Water; Human Serum Albumin (HSA); HEPES	**Different:** The formulations of the subject and predicate devices include the same types of chemical constituents; however, the formulations are not the identical. Differences in device formulations do not raise different questions of safety and effectiveness (S&E).

	K213293 **V-HEPES PLUS**	**K142991** **LifeGlobal Global Total w/HEPES w/HSA**	**Comparison**
Sterility	No growth	Sterile (SAL 10^{-3})	**Different:** The subject and predicate devices are both provided sterile; however, their specifications are different. This difference in sterility specification does not raise a different question of S&E.
pH	7.0-7.4	7.2–7.4	**Different:** The subject device has a lower pH range than the predicate device. This difference in pH range does not raise different questions of S&E.
Osmolality (mOsm/kg)	257-273	260-270	Similar
Mouse Embryo Assay (MEA)	1-Cell MEA:≥80% developed to expanded blastocysts at 96 h after 120-minute exposure	1-Cell MEA: ≥80% developed to expanded blastocysts at 96 h after one-hour exposure	**Different:** The duration of exposure of the subject and predicate devices to mouse embryos are not the same. This difference in MEA method due to expected worst-case exposure of media to oocytes/embryos during use does not raise different questions of S&E.
Endotoxin (EU/mL)	<0.25	≤0.5	**Different:** The subject device has a lower endotoxin level than the predicate device. This difference in endotoxin specifications does not raise different questions of S&E.
Sterilization	Aseptic filtration	Aseptic filtration	Same
Storage Condition	2-8°C	2-8°C	Same
Volume	100 mL	Not known	**Different:** The volume of the predicate device is not known; however, differences in device volume do not raise different questions of S&E.
Shelf-Life	12 months	10 weeks	**Different:** The subject device has a longer

	K213293 **V-HEPES PLUS**	**K142991** **LifeGlobal Global Total w/HEPES w/HSA**	**Comparison**
			shelf-life than the predicate device. Differences in shelf-life do not raise different questions of S&E.

As shown in the table above, there are differences in the indications for use statements and technological features of the subject and predicate devices. However, as stated in the table, the differences in indications for use do not represent a new intended use and the differences in technological features do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Performance Testing

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

- Biocompatibility testing was conducted in support of the subject device that will have direct contact with the patient during embryo transfer procedures. Testing was conducted in accordance with the 2020 FDA guidance *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
  - Vaginal Irritation per ISO 10993-23:2021

  The testing demonstrated the device formulation to be non-cytotoxic, non-sensitizing, and non-irritating.

- Sterile filtration and aseptic fill validation, per ISO 13408-1:2008 and ISO 13408-2:2018.

- Shelf-life testing was conducted to support the 12-month shelf-life for the subject device through demonstration that the product specifications (shown below) were met at time 0 and after accelerated aging in accordance with ASTM F1980-16:

  - Appearance: Pink rose color, no precipitates
  - pH: 7.0–7.4
  - Osmolality: 257–273 mOsm/kg
  - Endotoxin, per USP <85>: < 0.25 EU/mL
  - MEA testing, in accordance with the 2021 FDA guidance Mouse Embryo Assay for Assisted Reproduction Technology Devices: One-cell system: ≥80% embryos

developed to expanded blastocyst at 96 hours after 120-minute exposure to the subject device.
- Sterility, per USP <71>: No growth

- Transportation testing per ASTM D4169-16

Conclusions

The results of the performance testing described above demonstrate that V-HEPES PLUS is as safe and effective as the predicate device and support a determination of substantial equivalence.