September 13, 2024

VITROMED GmbH
c/o Greg Holland
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, California 92606

Re: K240176
Trade/Device Name: V-VITFREEZE and V-VITWARM
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Received: August 8, 2024

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 (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,

Michael T. Bailey -S

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)*
K240176

Device Name
V-VITFREEZE and V-VITWARM

Indications for Use *(Describe)*
V-VITFREEZE is intended for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

V-VITWARM is intended for use in the thawing of vitrified of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K240176

I. SUBMITTER

Applicant:	VITROMED GmbH
Address:	Raiffeisenstr. 15a, 40764 Langenfeld, Germany
Phone:	+49 2173-20041-30
Fax:	+49 2173-20041-58
Contact Person:	Deepesh Changat
Email:	qm@vitromed.com
Consultant Contact:	Greg Holland, Regulatory Specialists, Inc.
Email:	greg@regulatoryspecialists.com

Date Prepared: September 10, 2024

II. DEVICE

Trade Name:	V-VITFREEZE; V-VITWARM
Common Name:	Assisted Reproduction Media
Regulation Name:	Reproductive Media and Supplements
Regulation Number:	884.6180
Product Code:	MQL (Media, Reproductive)
Regulatory Class:	II

III. PREDICATE DEVICE

Vitrification Kit and Thawing Kit (K171748) from Kitazato Corporation. The predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

V-VITFREEZE AND V-VITWARM include a set of five media intended for use in the vitrification and thawing of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos as part of InVitro Fertilization (IVF) procedures.

V-VITFREEZE (2mL vials) includes two media components, Equilibration Solution (ES) and Vitrification Solution (VS), containing the cryoprotectants ethylene glycol, trehalose (only in VS), and dimethyl sulfoxide. During the vitrification process, embryos are first exposed to ES and then to VS.

Using this methodology, the permeating cryoprotectants can replace water in the oocyte or PN through blastocyst stage embryos prior to vitrification and storage in liquid nitrogen.

V-VITWARM (4mL vials) is composed of three media used stepwise for thawing and removing cryoprotectants from vitrified oocytes and PN through blastocyst stage embryos. It is composed of Thawing Solution (TS), Diluent Solution (DS) and Washing Solution (WS).

The base medium for the vitrification and thawing media includes water, salts, buffering agents, minerals, chelating agents, energy substrates, amino acids, hydroxypropyl cellulose, polymeric substance, gentamicin, and phenol red. Cryoprotectants in the media include ethylene glycol, (7.5% in ES and 15% in VS), DMSO (7.5% in ES and 15% in VS), and trehalose in VS, TS, and DS.

The five solutions in the V-VITFREEZE and V-VITWARM kit are aseptically filtered (storage vials sterilized by radiation) and provided in polypropylene vials with high density polyethylene screw caps. They have a shelf-life of 12 months when stored at 2-8°C. Media in the vials can be used for up to seven days after vial opening.

V. INDICATIONS for USE

V-VITFREEZE is intended for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

V-VITWARM is intended for use in the thawing of vitrified of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

VI. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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

Comparison Item	**K240176 Subject Device**	**K171748 Predicate Device**	**Comparison**
Indication for Use	V-VITFREEZE is intended for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3	The Vitrification Kit is indicated for use in the preparation, vitrification, and storage of oocytes (MII), pronuclear (PN)	There are differences in the wording of the indications for use statements for the subject and predicate device;

Comparison Item	K240176 Subject Device	K171748 Predicate Device	Comparison
	cleavage stage embryos and blastocyst stage embryos. V-VITWARM is intended for use in the thawing of vitrified of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.	zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos. The Thawing Kit is indicated for use in the preparation and thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos.	however, the intended uses of the subject and predicate device media are the same (i.e., vitrification and warming of oocytes and embryos).
Conditions for Use	Prescription Use Only	Prescription Use Only	**Same**
Kit components	V-VITFREEZE consists of Equilibration Solution (ES) and Vitrification Solution (VS). V-VITWARM includes TS (Thawing Solution), DS (Dilution Solution) and WS (Washing Solution).	The Vitrification Kit includes three media components, Basic Solution (BS), Equilibration Solution (ES) and Vitrification Solution (VS). The Vitrification Kit comes prepackaged with 4 Cryotop devices (Cryotop CL, Cryotop SC, or Cryotop US), and 2 Repro Plates. The Thawing Kit is composed of TS (Thawing Solution), DS (Dilution Solution) and WS (Wash Solution). The Thawing Kit comes pre-packaged with one Repro	The predicate device includes an additional basic solution component, equipment to conduct the procedure (plates), and a closed cryopreservation storage device that are different than the subject device. These differences do not raise different questions of S&E.

Comparison Item	K240176 Subject Device	K171748 Predicate Device	Comparison
		Plate, and two 35 mm dishes.	
Freeze Kit Formulation	Base medium (see Device Description section of summary) with cryoprotectants Ethylene Glycol, DMSO, and Trehalose	Medium 199, Ethylene Glycol, DMSO, Sucrose, Dextran Serum Supplement, Gentamicin	**Different:** The formulations of the subject and predicate devices are not the same. Differences in device formulations do not raise different questions of safety and effectiveness (S&E).
Thaw Kit Formulation	Base medium (see Device Description section of summary) with cryoprotectant Trehalose	Medium 199; Sucrose, Dextran Serum Supplement, Gentamicin	**Different:** The formulations of the subject and predicate devices are not the same. Differences in device formulations do not raise different questions of S&E.
pH	WS; DS; TS: 7.20 - 7.45 VS: 7.50 - 7.70 ES: 7.30 - 7.60	7.2-7.6	**Different:** The subject device has a higher pH range than the predicate device. These differences in pH specifications do not raise different questions of S&E.
Osmolality (mOsm/kg)	ES - 2300-3100 (1:10 dilution) VS: 4600-6150 (1:20 dilution) TS: 1250-1600 (1:4 dilution) DS - 730-930 (1:2 dilution) WS - 240-300 (No dilution)	Not available publicly	**Different:** The subject device and predicate devices have differences in osmolality specifications. These differences in osmolality specifications do not raise

Comparison Item	K240176 Subject Device	K171748 Predicate Device	Comparison
			different questions of S&E.
Bacterial Endotoxin	< 0.25 EU/mL	≤ 0.25 EU/mL	**Same**
Mouse Embryo Assay	1-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours.	1-Cell MEA: ≥ 80% expanded blastocyst after 96 hours	**Same**
Sterilization Method	Aseptic Filtration Vials are sterilized via radiation	Aseptic Filtration Vials are sterilized via radiation	**Same**
Shelf-Life	12 months	12 months	**Same**

As shown in the table above, there are differences in the indications for use statements and technological characteristics 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 characteristics do not raise different questions of safety and effectiveness.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

The following studies have been conducted in support of the substantial equivalence to the predicate device.

- Aseptic filtration and aseptic filling validation, per ISO 13408-1:2008 & A1:2013 and ISO 13408-2:2018.
- Vial radiation sterilization, per ISO 11137-1:2006 (including: Amendment 1 (2013) and Amendment 2 (2018)) Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices and ISO 11137-2:2013 - Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose [Including Amendment 1 (2022)].
- Shelf-life testing was conducted to support a 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 F1980-21:
  - Appearance: All of the solutions should be pink to rose color without precipitates
  - pH per USP <791>: WS, DS, TS: 7.20 - 7.45; VS: 7.50 - 7.70; ES: 7.30 - 7.60

- Osmolality per USP <785>: ES - 2300-3100 mOsm/kg (1:10 dilution), VS: 4600-6150 mOsm/kg (1:20 dilution), TS: 1250-1600 mOsm/kg (1:4 dilution), DS - 730-930 mOsm/kg (1:2 dilution), WS - 240-300 mOsm/kg (No dilution)
- Sterility per USP <71>: No microbial growth
- Bacterial endotoxin per USP <85>: < 0.25 EU/mL
- MEA per the 2021 FDA guidance *Mouse Embryo Assay for Assisted Reproduction Technology Devices*: 1-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours.

- Transportation testing per ASTM D4169-22 and cap/seal leak testing using a method equivalent to USP <1207.2> on transportation-conditioned devices.

VIII. CONCLUSION

The results of the performance testing described above demonstrate that V-VITFREEZE and V-VITWARM kit is as safe and effective as the predicate device and supports a determination of substantial equivalence.