March 20, 2024

VITROMED GmbH
% Greg Holland
Sr. Partner
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, California 92606

Re: K232125
Trade/Device Name: V-PVP
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: February 16, 2024
Received: February 20, 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.

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,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
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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)*
K232125

Device Name
V-PVP

Indications for Use *(Describe)*
V-PVP is intended for use as an aid in the immobilization and isolation of individual sperm cells prior to intracytoplasmic sperm injection (ICSI) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K232125

510(k) Owner	VITROMED GmbH Raiffeisenstr. 15a 40764 Langenfeld Germany Phone: +49 2173-20041-30 Facsimile: +49 2173-20041-58
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
Summary Date	March 18, 2024
Trade Name	V-PVP
Common Name	Assisted Reproduction Media
Regulation Name	Reproductive Media and Supplements
Regulation Number	884.6180
Product Code	MQL (Media, Reproductive)
Class	Class II
Predicate	InVitroCare, Inc. PVP - Polyvinylpyrrolidone K001967 The predicate device has not been subject to a design-related recall.

Device Description

V-PVP is intended for use as an aid in the immobilization and isolation of individual sperm cells prior to intracytoplasmic sperm injection (ICSI) procedures.

V-PVP is a clear solution with a formulation consisting of polyvinylpyrrolidone, human serum albumin, physiological salts, HEPES Human Tubal Fluid (HTF), pyruvate, lactate, glucose, and gentamicin. This product is aseptically filtered into 2 mL bottles with caps made from polypropylene copolymer and is provided in a volume of 0.5 mL. V-PVP has a one-year shelf-life when stored as recommended and can be used for up to seven days after opening.

Indications for Use

V-PVP is intended for use as an aid in the immobilization and isolation of individual sperm cells prior to intracytoplasmic sperm injection (ICSI) procedures.

Comparison of intended use and technological characteristics of the subject and predicate devices

A comparison of the intended use and technological characteristics of the subject device and the predicate device is shown in the table below:

	V-PVP (subject device)	**InVitroCare, Inc. PVP K001967**	**Comparison**
Indications for Use	V-PVP is intended for use as an aid in the immobilization and isolation of individual sperm cells prior to intracytoplasmic sperm injection (ICSI) procedures.	PVP (polyvinylpyrrolidone) reagent is intended for use in assisted reproductive technology procedures involving the manipulation of gametes. Specifically, PVP is intended for use as a medium for the immobilization and isolation of single sperm cells during intracytoplasmic sperm injection (ICSI) procedures.	There are differences in the subject and predicate device indications for use statements; however, both have the same intended use (i.e., for immobilization and isolation of a single sperm for use in ICSI fertilization procedures).
Conditions of Use	Rx Only	Rx Only	Same
Device materials	Polyvinylpyrrolidone, human serum albumin, physiological salts, HEPES HTF, pyruvate, lactate, glucose, gentamicin	Polyvinylpyrrolidone, human serum albumin, HEPES HTF, sodium bicarbonate, gentamicin	**Different -** The formulas of the subject and predicate devices are not the same. Differences in media formulations do not raise different questions of safety and effectiveness (S&E).
Concentrations	7%	10%	**Different -** The PVP concentration in the subject device is lower than in the predicate device. Differences in PVP concentrations do not raise different questions of S&E.
Aseptically Filtered	Yes	Yes	Same
Sterility	Sterile (No Growth) USP <71>	Sterile (No Growth) USP <71>	Same

	V-PVP (subject device)	InVitroCare, Inc. PVP K001967	Comparison
pH	7.25-7.45	7.25-7.45	Same
Osmolality (mOSM/kg)	300-330	Unknown	**Different -** The osmolality acceptance specification for the predicate device is not known; however, this difference does not raise different questions of S&E.
Endotoxin (EU/ml)	<0.5	Unknown	**Different -** The endotoxin acceptance specification for the predicate device is not known; however, this difference does not raise different questions of S&E.
Compatibility with human sperm	Human Sperm Survival Assay (HSSA): ≥ 80% of Control Motility at 24hr after 30 min contact to V-PVP	Unknown	**Different –** Compatibility of the predicate device with human sperm is not known; however, this difference does not raise different questions of S&E.
Mouse Embryo Assay (MEA)	1-Cell System: ≥80% of embryos developed to expanded blastocyst at 96h after a 30-minute contact to V-PVP	≥80% 1-cell to expanded blastocyst within 96 hours.	**Different -** The MEA specifications are different between the subject and predicate devices; however, the differences do not raise different questions of S&E.
Shelf Life	1 Year 7 days (Open Vial)	1 Year	Same

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, the subject and predicate device have the same 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:

- Sterile filtration and aseptic fill validation, per ISO 13408-1:2008 – Aseptic Processing of Health Care Products – Part 1 General Requirements (including Amendment 1 (2013)) and ISO 13408- 2:2018 – Aseptic Processing of Health

Care Products – Part 2 Sterilizing Filtration.

- 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 F1980-21. Testing was also included on aged samples demonstrating that medium in bottles can maintain their specifications after seven days of simulated use conditioning after bottle opening. Testing conducted is shown below:

    - Clarity/Color: Pink rose color, no precipitates
    - pH, per USP<791>: 7.25–7.45
    - Osmolality, per USP<785>: 300-330 mOsm/kg
    - Endotoxin, per USP <85>: < 0.5 EU/mL
    - MEA: 1-Cell System: ≥80% of embryos developed to expanded blastocyst at 96h after 30-minute contact to V-PVP
    - HSSA: ≥ 80% of control motility at 24h after 30 minute contact to V-PVP
    - Sterility, per USP<71>: No growth

- Transportation testing per ASTM D4169-22 and USP<1207>

- Comparative assessment of sperm immobilization of the subject device (7% PVP) to a 10% PVP comparator device.

Conclusions

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