March 21, 2025

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

Re: K241833
Trade/Device Name: V-GRAD (V-GRAD Kit, V-GRAD 40, V-GRAD 80, V-GRAD 100)
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Received: February 19, 2025

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241833

Device Name

V-GRAD (V-GRAD Kit, V-GRAD 40, V-GRAD 80, V-GRAD 100)

Indications for Use *(Describe)*

V-GRAD is intended for separation of motile sperm from ejaculates by the density gradient method for use in assisted reproduction 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.

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510(k) Summary
K241833

510(k) Owner	VITROMED GmbH Raiffeisenstr. 15a 40764 Langenfeld Germany Phone: +49 2173-20041-30 Facsimile: +49 2173-20041-58 Contact: Ines Diener Email: ines@vitromed.com
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 21, 2025
Trade Name	V-GRAD (V-GRAD Kit, V-GRAD 40, V-GRAD 80, V-GRAD 100)
Common Name	Assisted Reproduction Media
Classification Name	Reproductive Media and Supplements
Regulation	884.6180
Class	Class II
Product Code	MQL (Media, Reproductive)
Predicate Device	K153267 ORIGIO A/S ORIGIO Gradient 100, ORIGIO Gradient 90, ORIGIO Gradient 40/80 The predicate device has not been subject to a design-related recall.

Device Description

V-GRAD is a sterile colloidal suspension with silicate particles, stabilized with covalently bound hydrophilic silanes that is intended for separation of motile sperm from ejaculates by the density gradient method for use in assisted reproduction procedures. Available as a 100 % stock solution (V-GRAD 100) and as 40% or 80% ready-to-use solutions (V-GRAD 40 and V-GRAD 80) with HEPES buffered Human Tubular Fluid (HTF) medium.

V-GRAD 100 is a stock solution for preparing a density gradient system for semen preparation. The V-GRAD Kit consists of two bottles of V-GRAD 40 and V-GRAD 80.

V-GRAD is aseptically filtered and provided in pre-sterilized 12 mL glass bottles closed with flourotec rubber stoppers and flip-tear off caps or 100 mL PET(G) bottles closed with HDPE screw caps. V-GRAD has a shelf-life of one year when stored at 2-8°C and can be used for up to seven days after bottle opening.

Indications for Use

V-GRAD is intended for separation of motile sperm from ejaculates by the density gradient method for use in assisted reproduction procedures.

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:

	K241833 V-GRAD (V-GRAD Kit V-GRAD 40, V-GRAD 80, V-GRAD 100)	**K153267 ORIGIO Gradient 100, ORIGIO Gradient 90, ORIGIO Gradient 40/80**	**Comparison**
Indications for Use	V-GRAD is intended for separation of motile sperm from ejaculates by the density gradient method for use in assisted reproduction procedures.	ORIGIO® Gradient™ 100, ORIGIO® Gradient™ 90 and ORIGIO® Gradient™ 40/80 are for the separation of motile sperm from the ejaculate by the density gradient method.	There are differences in the wording of the indications for use statements for the subject and predicate device; however, both have the same intended use, i.e., separation of motile sperm from the ejaculates by the density gradient method.
Conditions for Use	Prescription Use Only	Prescription Use Only	Same

	K241833 V-GRAD (V-GRAD Kit V-GRAD 40, V-GRAD 80, V-GRAD 100)	**K153267 ORIGIO Gradient 100, ORIGIO Gradient 90, ORIGIO Gradient 40/80**	**Comparison**
Available Variants	- V-GRAD 100 - V-GRAD 40 - V-GRAD 80 - V-GRAD Kit (containing V-GRAD 80 and V-GRAD 40)	- ORIGIO Gradient™ 100 - ORIGIO Gradient™ 90 - ORIGIO Gradient™ 40/80	**Different:** There are differences in the medium variants for the subject and predicate devices; however, these differences do not raise different questions of S&E.
Gradient Medium Density (% silica)	40%, 80%, 100%	40%, 80%, 90%, 100%	**Different:** The gradient medium density for the subject and predicate devices is different; however, this difference does not raise different questions of S&E.
Formulation	Physiological salts; energy substrates; buffering agents; silane-coated silica; gentamicin sulfate; phenol red; water	Not known	**Different:** The formulation of the predicate device is not known; however, the differences in media product formulations do not raise different questions of S&E.
Sterilization	Aseptic filtration	Aseptic filtration	Same
Sterility	No growth	No growth	Same
pH	7.20 – 7.90	7,95 – 8.495	**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.

	K241833 V-GRAD (V-GRAD Kit V-GRAD 40, V-GRAD 80, V-GRAD 100)	**K153267 ORIGIO Gradient 100, ORIGIO Gradient 90, ORIGIO Gradient 40/80**	**Comparison**
Endotoxin (EU/ml)	<0.5	<0.8	**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.
Osmolality (mOsm/kg)	310-340 (V-GRAD 40) 310-340 (V-GRAD 80) 300-330 (V-GRAD 100)	317-333 (Origio Gradient™ 40) 297-313 (Origio Gradient™ 80, 90 and 100)	Similar
Density (g/cm^3)	1.050-1.061 (V-GRAD 40) 1.100-1.111 (V-GRAD 80) 1.125-1.136 (V-GRAD 100)	1.048-1.062 (Origio Gradient™ 40) 1.098-1.112 (Origio Gradient™ 80) 1.105-1.119 (Origio Gradient™ 90) 1.123-1.137 (Origio Gradient™ 100)	Similar
Storage	2-8°C	2-8°C	Same
HSSA	≥ 80% of control motility at hours after 1 hour exposure to test medium	≥ 80% of control	**Different:** The HSSA exposure time for the predicate device is not known; however, this difference does not raise different questions of S&E.
Shelf Life	1 Year	20 weeks (Origio 100) 36 weeks (Origio 40, 80, and 90)	**Different:** The subject device has a longer shelf life than the predicate device. Difference does 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, 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:

- Aseptic filtration and aseptic filling 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:

  - Appearance: Pink rose color (V-GRAD 40), light pink color (V-GRAD 80), colorless (V-GRAD 100)
  - pH: 7.2-7.9
  - Osmolality (mOsm/kg): 310-340 (V-GRAD 40 and V-GRAD 80), 300-330 (V-GRAD 100)
  - Endotoxin (EU/mL): <0.5
  - Density (g/cm^3): 1.050-1.061 (V-GRAD 40), 1.100-1.111 (V-GRAD 80), 1.125-1.136 (V-GRAD 100)
  - Human Sperm Survival Assay (HSSA): ≥ 80% of control motility at 24 hours after 1 hour exposure to test medium
  - Sterility, per USP <71>: No growth

- Transportation testing per ASTM D4169-22 and USP <1207.2>.

- Sperm separated using the subject device were evaluated for motility, morphology, and purity. The results demonstrate that the subject device has comparable performance with the predicate device and other cleared devices of this type.

Conclusions

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