January 28, 2020

VITROMED GmbH
% Robyn Scopis
CEO
Regulatory Specialists, Inc.
628 El Mirador Drive
Fullerton, CA 92835

Re: K192146
Trade/Device Name: V-DENUPET
Regulation Number: 21 CFR 884.6130
Regulation Name: Assisted Reproduction Microtools
Regulatory Class: II
Product Code: MQH
Dated: December 16, 2019
Received: December 30, 2019

Dear Robyn Scopis:

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.
Acting 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)*
K192146

Device Name
V-DENUPET

Indications for Use *(Describe)*
V-DENUPET is used for the removal of cumulus oocyte complexes (COC) from an oocyte prior to Intracytoplasmic Sperm Injection (ICSI) and In Vitro Fertilization (IVF) as well as for the handling of oocytes and embryos during assisted reproductive techniques (ART). V-DENUPET is not intended for biopsy of cells from oocytes or 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.

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510(k) Summary
K192146

510(k) Owner	VITROMED GmbH Hans-Knöll-Str. 6 07745 Jena Germany Franziska Buch Phone: +49 36 41 5 39 19 76 Facsimile: +49 36 41 5 39 19 77 Email: qm@vitromed.com
Contact person	Robyn Scopis Regulatory Specialists, Inc. 628 El Mirador Drive Fullerton, CA 92835 Phone: 949.262.0411 Fax: 949.552.2821 Email: robyn@regulatoryspecialists.com
Date Prepared	January 27, 2020
Product Information	
Trade Name	V-DENUPET
Common Name	Assisted reproduction micropipette
Regulation Name	Assisted Reproduction Microtools
Regulation Number	884.6130
Regulatory Class	Class II
Product Code	MQH - Microtools, Assisted Reproduction (Pipettes)
Predicate	Research Instruments Ltd. EZ-Tip Vial of 20 K161275 The predicate device has not been subject to a design-related recall.

Device Description

The V-DENUPET is a polycarbonate micropipette. All tips are 90 mm in length, and depending on the size of the tip have a volumetric capacity of 20-25 µl. All pipettes have an outer diameter of 900 µm at the proximal end that is connected to an aspiration device.

The V-DENUPET is supplied in a range of inner diameter sizes at the distal end as shown below:

- Sizes 125 µm, 135 µm, 140 µm, 150 µm, and 175 µm are suitable for oocyte denudation.

- Sizes 175 µm, 200 µm, 275 µm, 300 µm, and 600 µm are suitable for oocyte and embryo handling.

V-DENUPET micropipettes are radiation sterilized and provided in a sterile pouch containing a polypropylene vial containing 10 micropipettes. Each pipette is for single-use only.

Indications for Use

V-DENUPET is used for the removal of cumulus oocyte complexes (COC) from an oocyte prior to Intracytoplasmic Sperm Injection (ICSI) and In Vitro Fertilization (IVF) as well as for the handling of oocytes and embryos during assisted reproductive techniques (ART). V-DENUPET is not intended for biopsy of cells from oocytes or embryos.

Technological Characteristics

The table below provides a comparison of the indications for use and technological characteristics of the subject device and predicate device:

	Subject Device **V-DENUPET**	**Predicate Device** **EZ-Tip Vial of 20** **K161275**	**Comparison**
Indications for Use	V-DENUPET is used for the removal of cumulus oocyte complexes (COC) from an oocyte prior to Intracytoplasmic Sperm Injection (ICSI) and In Vitro Fertilization (IVF) as well as for the handling of oocytes and embryos during assisted reproductive techniques (ART). V-DENUPET is not intended for biopsy of cells from oocytes or embryos.	EZ-Tip pipettes are for denudation, i.e. removing the cumulus from an oocyte prior to Intracytoplasmic Sperm Injection (ICSI) and In Vitro Fertilization (IVF) and for handling gametes, embryos and biopsied cells (polar bodies, blastomeres and trophectoderm) during assisted reproductive techniques (ART). EZ-Tips are not intended for biopsy of cells from oocytes or embryos.	**Different** Both subject and predicate devices are intended for use in oocyte denudation procedures and handling oocytes and embryos; however, the predicate can also be used for handling biopsied cells. This difference does not represent a different intended use between the subject and predicate device.
Materials	Polycarbonate	Polycarbonate	**Same**
Sterility	Sterile ($10^{-}6$) Gamma Irradiated	Sterile ($10^{-}6$) Gamma Irradiated	**Same**

Proximal Outer Dimension	900 µm	900 µm	**Same**
Distal Inner Diameter	Size range 125 µm to 600 µm	Size range 75 µm to 600 µm	**Different** The V-DENUPET is within the cleared range of the predicate device. This difference does not raise different questions of safety or effectiveness (S&E).
Length	90 mm	90 mm	**Same**
Mouse Embryo Assay (MEA)	1-Cell MEA ≥80% hatched blastocysts at 96 h	1-Cell MEA ≥80% hatched blastocysts at 120 h	**Different** The Mouse Embryo Assay (MEA) assessment time is shorter for the V-DENUPET, but is the standard assessment time for this assay. Therefore, this difference does not raise different questions of S&E.
Endotoxin (LAL)	<0.05 EU/device	<20 EU/device	**Different** The endotoxin specification for the subject device is lower than the predicate device. This difference does not raise different questions of S&E..
Usage	Single Use Only	Single Use Only	**Same**

As shown in the table above, the subject and predicate devices have different indications for use statements; however, the intended uses of the predicate and subject devices are the same (i.e., denudation of oocytes and handling of oocytes and embryos during assisted reproduction technology procedures).

In regards to technological characteristics, the subject and predicate devices have similarities (e.g., material, length, diameter at the proximal end, sterilization method, etc.); however, as noted in the table above, technological differences were identified between the subject and predicate devices (e.g., distal end tip diameter and specifications for MEA and endotoxin testing). As stated in the table, the technological differences between the subject and predicate devices do not raise different questions of safety and effectiveness.

Non-Clinical Performance Testing

The following performance data were provided in support of the substantial equivalence determination:

1. Sterilization Validation per ISO 11137-1:2006 and ISO 11137-2:2013

2. Package Integrity Testing:
    a. Seal strength – method equivalent to ASRM F88/F88M-15
    b. Burst Testing – ASTM 2054-07
    c. Dye Penetration Testing – ASTM F1929-98

3. Shelf Life testing assessing device function at Time 0 and at 36 months:
    a. MEA testing - 1-Cell MEA: ≥80% hatched blastocyst at 96h
    b. Endotoxin (LAL, USP<85>) - <0.05 EU/device
    c. Device dimensions
    d. Appearance/cleanliness

Conclusion

The results of the testing described above demonstrate that the V-DENUPET is substantially equivalent to the predicate device.