May 26, 2023

VITROMED GmbH
% Greg Holland
Consultant
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606

Re: K222606
Trade/Device Name: V-HYADASE
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: April 21, 2023
Received: April 24, 2023

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,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
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General Hospital and Urology Devices
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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)*
K222606

Device Name
V-HYADASE

Indications for Use *(Describe)*
V-HYADASE is intended for the enzymatic removal of cumulus and corona radiata cells from oocytes 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.

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510(k) Summary
K222606

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
Submission Date	May 23, 2023
Trade Name	V-HYADASE
Common Name	Assisted Reproduction Media
Regulation Name	Reproductive Media and Supplements
Regulation Number	884.6180
Product Code	MQL (Media, Reproductive)
Class	Class II
Predicate	Origio A/S Synvitro Hyadase K200680 The predicate device has not been subject to a design-related recall.

Device Description

V-HYADASE is an assisted reproduction medium intended for the enzymatic removal of cumulus and corona radiata cells from oocyte prior to Intracytoplasmic Sperm Injection (ICSI) procedures. The medium is aseptically filtered and provided in a volume of 1 mL in pre-sterilized 2 mL polypropylene copolymer (PPCO) bottles with PPCO caps. V-HYADASE 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. Additional information on the formulation and specifications of V-HYADASE are provided in the Comparison of the Subject and Predicate Device Intended Use and Technological Characteristics section of this summary.

Indications for Use

V-HYADASE is intended for the enzymatic removal of cumulus and corona radiata cells from oocytes prior to intracytoplasmic sperm injection (ICSI) 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 device are described in the table below:

	Subject Device V-HYADASE K222606	**Predicate Device Origio A/S SynVitro Hyadase K200680**	**Comparison**
Indications	V-HYADASE is intended for the enzymatic removal of cumulus and corona radiata cells from oocytes prior to intracytoplasmic sperm injection (ICSI) procedures.	SynVitro Hyadase is for the removal of the cumulus complex and corona radiata surrounding the oocyte in preparation for ICSI.	There are differences in the wording of the subject and predicate device indications for use statements; however, both have the same intended use (i.e., for removal of cumulus and corona radiata cells from oocytes prior to ICSI fertilization).
Prescription Use Only	Yes	Yes	**Same**
Formulation	Water HEPES Glucose, D- (+) Calcium lactate Gentamicin sulfate HSA Sodium Bicarbonate Physiological Salts Essential Amino Acids Non-Essential Amino Acids Phenol red Hyaluronidase (Bovine Source) Vitamin Citric Acid Chelating agent Sodium Pyruvate	Hyaluronidase (non-bovine source) Glucose Sodium pyruvate Calcium chloride Magnesium sulphate Sodium chloride HEPES	**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).
Sterilization	Aseptic Filtration, USP <71> - No Growth	Aseptic Filtration, USP <71> - No Growth	**Same**
pH	7.20-7.40	7.150-7.449	**Similar**
Osmolality (mOSM/kg)	257-273	272-288	**Similar**

Mouse Embryo Assay (MEA)	1-Cell System: ≥80% of embryos developed to expanded blastocyst at 96h after a 4-min exposure to V-HYADASE	1-Cell MEA ≥80% developed within 96 hours after a 15-second exposure to SynVitro Hyadase	**Different –** The subject device specification includes a longer exposure of the medium to mouse embryos. A longer exposure does not raise different questions of S&E.
Endotoxin (EU/ml)	<0.5	≤0.5	**Similar**
Hyaluronidase enzyme activity	50-120 IU/mL	40-120 IU/mL	**Similar**
Shelf Life	1 Year 7 days (Open Vial)	1 Year 7 days (Open Vial)	**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>: 7.2–7.4
    - Osmolality, per USP<785>: 257–273 mOsm/kg
    - Endotoxin, per USP <85>: < 0.5 EU/mL
    - MEA: 1-Cell System: ≥80% of embryos developed to expanded blastocyst at 96h after 4-min exposure to V-HYADASE
    - Sterility, per USP<71>: No growth
    - Hyaluronidase Activity: 50-120 IU/mL

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

Conclusions

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