December 18, 2024

ARTSMedia Denmark ApS
Tina Andersen
Executive Director RA/QA
Kongevejen 149
Virum, 2830
DENMARK

Re: K241095
Trade/Device Name: ARTSMedia Semen Wash Medium
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: November 21, 2024
Received: November 22, 2024

Dear Tina Andersen:

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.

510(k) Number *(if known)*
K241095

Device Name
ARTSMedia Semen Wash Medium

Indications for Use *(Describe)*
ARTSMedia Semen Wash Medium (AM Semen Wash) is intended for washing of sperm and for sperm swim-up procedures. The medium can also be used for IUI (Intra Uterine Insemination).

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
K241095

510(k) Owner/Contact details	ARTSMedia Denmark ApS Kongevejen 149 2830 Virum Denmark Tina Andersen Phone: +45 53535199
Date Prepared	December 18, 2024
Trade Name	ARTSMedia Semen Wash Medium
Common Name	Reproductive media and supplements
Classification Name	Media, Reproductive
Regulation Number	21 CFR 884.6180
Product Code	MQL
Predicate Device	K212410 VitaVitro® Sperm Washing Medium This predicate device has not been subject to a design related recall.

Device Description

ARTSMedia Semen Wash Medium (AM Semen Wash) is intended for washing of sperm and for sperm swim-up procedures. The medium can also be used for IUI (Intra Uterine Insemination).

ARTSMedia Semen Wash Medium consists of physiological salts, energy substrates, buffering agents, Gentamicin Sulphate, and water.

Furthermore, ARTSMedia Semen Wash Medium is aseptically filtered and provided in a volume of 20 mL, 50 mL, and 100 mL in pre-sterilized glass bottles closed with Fluorotec-coated stoppers and aluminum caps. The ARTSMedia Semen Wash Medium is tested for pH, osmolality, endotoxin, sterility, and sperm toxicity before lot release. The device has a shelf-life of 18 months when stored at 2-8°C and is for single-use only.

Indications for Use

ARTSMedia Semen Wash Medium (AM Semen Wash) is intended for washing of sperm and for sperm swim-up procedures. The medium can also be used for IUI (Intra Uterine Insemination).

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:

Parameters	K241095 ARTSMedia Semen Wash Medium	K212410 VitaVitro® Sperm Washing Medium	Comparison
Indications for Use	ARTSMedia Semen Wash Medium (AM Semen Wash) is intended for washing of sperm and for sperm swim-up procedures. The medium can also be used for IUI (Intra Uterine Insemination).	VitaVitro® Sperm Washing Medium is intended for preparation and washing of sperm for use in assisted reproduction procedures. VitaVitro® Sperm Washing Medium is also intended for use in intrauterine insemination procedures.	The subject device indications for use statement is not identical to the predicate device. However, the intended use of the subject and predicate device is the same (i.e., for sperm washing, preparation, and intrauterine insemination procedures).
Conditions for Use	Prescription Use Only	Prescription Use Only	**Same**
Formulation	Gentamicin sulphate Glucose HEPES Human Serum Albumin Sodium pyruvate Sodium bicarbonate Calcium chloride Magnesium sulphate Magnesium chloride Potassium chloride Sodium chloride Potassium phosphate Calcium lactate Insulin Sodium selenite Ethanolamine Water	Gentamicin sulphate Glucose HEPES Human Serum Albumin Sodium Pyruvate Sodium Lactate Taurine Alanyl Glutamine EDTA Water	**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).
Sterilization	Aseptic filtration	Aseptic filtration	**Same**
Sterility	No growth	No growth	**Same**
pH	7.2-7.6	7.2-7.6	**Similar**
Osmolality (mOsm/kg)	270 – 300	270 – 300	**Same**
Human Sperm Survival Assay (% motility compared with control after 24 hours)	≥ 80%	≥ 80%	**Same**

Endotoxin (EU/ml)	<0.25	<0.25	**Same**
Storage Condition	2-8°C	2-8°C	**Same**
Shelf life	18 months	2 years	**Different**: The shelf-life of the subject and predicate device is not the same. Differences in shelf-life do not raise different questions of S&E.

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.

Summary of Non-Clinical Performance Testing

The following studies have been performed to support substantial equivalence to the predicate device:

- Biocompatibility testing was conducted in support of the subject device that will have direct contact with the patient during IUI (Intra Uterine Insemination). Testing was conducted in accordance with the 2023 FDA guidance Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process. Testing included:

    - Cytotoxicity per ISO 10993-5:2009
    - Sensitization per ISO 10993-10:2021
    - Vaginal Irritation per ISO 10993-23:2021

    The testing demonstrated the device formulation to be non-cytotoxic, non-sensitizing, and indicating minimally irritating according to irritation index calculation.

- Aseptic filtration and aseptic filling validation, per ISO 13408-1:2008 & A1:2013 and ISO 13408- 2:2018.

- Shelf-life testing was conducted under accelerated aging conditions per ASTM F1980-21 to support the 18-month shelf-life for the subject device through demonstration that the product specifications (shown below) were met at time 0 and at 18 months.

    - Appearance: Clear and particulate free
    - pH, per USP <791>: 7.2–7.6
    - Osmolality, per USP <785>: 270–300 mOsm/kg
    - Endotoxin, per USP <85>: < 0.25 EU/mL
    - Human Sperm Survival Assay (% motility compared with control): ≥ 80%
    - Sterility, per USP <71>: No growth

- Transportation testing per ASTM D4169-22 (DC-13) and cap/seal leak testing using a method equivalent to USP <1207.2> on transportation-conditioned devices.

Conclusions

The results of the performance testing described above demonstrate that AM Semen Wash is as safe and effective as the predicate device and supports a determination of substantial equivalence.