February 10, 2023

ARTSMedia Denmark ApS
Lotte Stroebech
CEO
Kongevejen 149
Virum, 2830
Denmark

Re: K220715
Trade/Device Name: ARTSMedia In Vitro Culture Medium (AM-IVC Medium)
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: January 9, 2023
Received: January 11, 2023

Dear Lotte Stroebech:

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220715

Device Name
ARTSMedia In Vitro Culture Medium
(AM-IVC Medium)

Indications for Use *(Describe)*
ARTSMedia In Vitro Culture Medium (AM-IVC Medium) is a culture medium intended for in vitro fertilization and in vitro culture of human gametes and embryos from fertilization until the blastocyst stage of development (day 5). The medium can also be used for embryo transfer.

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.

510(k) Summary
K220715

510(k) Owner	ARTSMedia Denmark ApS Kongevejen 149 2830 Virum Denmark Lotte Stroebech Phone: +45 53504530
Date Prepared	February 8, 2023
Trade Name	ARTSMedia In Vitro Culture Medium (AM-IVC Medium)
Common Name	Assisted Reproduction Media
Regulation Name	Reproductive Media and Supplements
Regulation Number	21 CFR 884.6180
Class	Class II
Product Code	MQL (Media, Reproductive)
Predicate Device	K133707 ORIGIO a/s SAGE 1-StepTM supplemented with Human Serum Albumin The predicate device has not been subject to a design-related recall.

Device Description
ARTSMedia In Vitro Culture Medium (AM-IVC Medium) is a medium for in vitro fertilization and culture of human gametes and embryos from fertilization until the blastocyst stage of development (day 5). The medium can also be used for embryo transfer procedures.

The medium is aseptically filtered and provided in in a volume of 10 mL in pre-sterilized 10 mL glass bottles closed with Fluorotec-coated stoppers and aluminum caps. The medium has a shelf-life of 10 months when stored at 2-8^{o}C and is for single-use only. Additional information on the formulation and specifications of AM-IVC Medium are provided in the Comparison of the Subject and Predicate Device Intended Use and Technological Characteristics section of this summary.

Indications for Use
ARTSMedia In Vitro Culture Medium (AM-IVC Medium) is a culture medium intended for in vitro fertilization and in vitro culture of human gametes and embryos from fertilization until the blastocyst stage of development (day 5). The medium can also be used for embryo transfer.

Comparison of the Subject and Predicate Device Intended Use and Technological Characteristics

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

Parameters	K220715 AM-IVC Medium Subject Device	K133707 SAGE 1-Step™ Predicate Device	Comparison
Indications for Use	ARTSMedia In Vitro Culture Medium (AM-IVC Medium) is a culture medium intended for in vitro fertilization and in vitro culture of human gametes and embryos from fertilization until the blastocyst stage of development (day 5). The medium can also be used for embryo transfer.	This product is intended for the *in vitro* fertilization and culture of human gametes and embryos from fertilization until Day 5/6 of development. The media can also be used for embryo transfer.	The subject device indications for use statement is not identical to the predicate device, as it is only for use up to day 5 of development. However, the overall intended use of the subject and predicate device is the same (i.e., for fertilization and culture of embryos to the blastocyst stage of development and for use in embryo transfer procedures).
Conditions for Use	Prescription Use Only	Prescription Use Only	**Same**
Formulation	Physiological Salts Amino Acids Vitamins Calcium Lactate EDTA Gentamicin Sulphate Glucose L-glutamine Human Serum Albumin (HSA) Sodium Bicarbonate Sodium Hyaluronate Sodium Pyruvate Phenol Red Selenite Ethanolamine Sodium citrate Human Insulin (from yeast)	Physiological Salts Amino Acids Calcium -L-Lactate EDTA Gentamicin Sulphate Glucose L-glutamine Human Serum Albumin (HSA) Sodium Bicarbonate Sodium Hyaluronate Sodium Pyruvate Phenol Red	**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	7.2-7.45	7.2-7.4	**Similar**
Osmolality (mOsm/kg)	257-275	257-273	**Similar**
Mouse Embryo Assay (MEA)	1-cell Mouse Embryo Assay (MEA) ≥ 80% embryos developed to expanded blastocysts at 96 hours.	1-cell MEA ≥ 80%	**Similar**
Endotoxin (EU/ml)	<0.05	<0.15	**Different:** The subject device has a lower endotoxin level than the predicate device. This difference in endotoxin specification does not raise different questions of S&E.
Shelf life	10 months	14 weeks	**Different**: The subject device has a longer shelf-life than the predicate device. 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 embryo transfer procedures. Testing was conducted in accordance with the 2020 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 10993-10:2010
  - Vaginal Irritation per ISO 10993-10:2010

  The testing demonstrated the device formulation to be non-cytotoxic, non-sensitizing, and non-irritating.

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

- Shelf-life testing was conducted to support a 10-month shelf-life for the subject device through demonstration that the product specifications (shown below) were met at time 0 and after 10 months of real-time aging:

    - Appearance: Clear and particulate free
    - pH, per USP <791>: 7.2–7.45
    - Osmolality, per USP <785>: 257–275 mOsm/kg
    - Endotoxin, per USP <85>: < 0.05 EU/mL
    - MEA testing, in accordance with the 2021 FDA guidance Mouse Embryo Assay for Assisted Reproduction Technology Devices: 1-Cell Mouse Embryo Assay (MEA) ≥80% embryos developed to expanded blastocyst at 96 hours.
    - Sterility, per USP <71>: No growth

- Transportation testing per ASTM D4169-22 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-IVC Medium is as safe and effective as the predicate device and supports a determination of substantial equivalence.