



December 18, 2024

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

Re: K241132
Trade/Device Name: ARTSMedia Oocyte Aspiration 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

Indications for Use

510(k) Number (if known)

K241132

Device Name

ARTSMedia Oocyte Aspiration Medium

Indications for Use (Describe)

ARTSMedia Oocyte Aspiration Medium (AM-Oocyte Aspiration) is intended for retrieval of human oocytes by follicular aspiration or flushing. The medium can also be used for washing of oocytes.

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 K241132

510(k) Owner/Contact details	ARTSMedia Denmark ApS Kongevej 149 2830 Virum Denmark Tina Andersen Phone: +45 53535199
Date Prepared	December 12, 2024
Trade Name	ARTSMedia Oocyte Aspiration Medium
Common Name	Assisted Reproduction Media
Classification Name	Reproductive media and supplements
Regulation Number	21 CFR 884.6180
Product Code	MQL
Predicate Device	K991327 Medi-Cult Flushing Medium
	The predicate device has not been subject to a design-related recall.

Device Description

ARTSMedia Oocyte Aspiration Medium (AM Oocyte Aspiration) is intended for retrieval of human oocytes by follicular aspiration or flushing. The medium can also be used for washing of oocytes.

ARTSMedia Oocyte Aspiration Medium consists of physiological salts, energy substrates, buffering agents, Human Serum Albumin, Gentamicin Sulphate, and water.

Furthermore, ARTSMedia Oocyte Aspiration 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 Oocyte Aspiration Medium is tested for pH, osmolality, embryotoxicity, endotoxin, and sterility, 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 Oocyte Aspiration Medium (AM-Oocyte Aspiration) is intended for retrieval of human oocytes by follicular aspiration or flushing. The medium can also be used for washing of oocytes.

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	K241132 ARTSMedia Oocyte Aspiration Medium	K991327 Medi-Cult Flushing Medium	Comparison
Indications for Use	ARTSMedia Oocyte Aspiration Medium (AM-Oocyte Aspiration) is intended for retrieval of human oocytes by follicular aspiration or flushing. The medium can also be used for washing of oocytes.	Flushing Medium is used for oocyte retrieval and oocyte washing and for holding throughout oocyte recovery.	Same Intended Use
Conditions for Use	Prescription Use Only	Prescription Use Only	Same
Formulation	Calcium chloride 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 Ethanalamine Milli RX Water	Earl's Balances Salt Solution (EBSS) Sodium Pyruvate Assisted Reproduction Technology Supplement (ARTS) HEPES Sodium Bicarbonate Human Serum Albumin (HAS) Penicillin Streptomycin 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)
Sterility	No growth	No growth	Same
pH	7.2-7.6	Not known	Different: The pH acceptance specification for the predicate device is not known; however, this difference does not raise different questions of S&E.
Osmolality (mOsm/kg)	270 – 300	Not known	Different: The osmolality acceptance specification for the predicate device is not

Parameters	K241132 ARTSMedia Oocyte Aspiration Medium	K991327 Medi-Cult Flushing Medium	Comparison
			known; however, this difference does not raise different questions of S&E.
Mouse Embryo Assay (MEA)	1-Cell MEA $\geq$ 80% embryos developed to expanded blastocysts at 96 hours following 60 minutes exposure to ARTSMedia Oocyte Aspiration Medium.	Two cell assay $\geq$ 80% hatching	Different: The MEA methods used for the subject and predicate are different; however, this difference does not raise different questions of S&E.
Endotoxin (EU/ml)	<0.25	Not know	Different: The endotoxin acceptance specification for the predicate device is not known; however, this difference does not raise different questions of S&E.
Sterilization	Aseptic filtration	Aseptic filtration	Same
Shelf life	18 months	Not known	Different: The shelf-life of the predicate device is not known; however, this difference does not raise different questions of S&E.

As shown in the table above, there are differences in the indications for use statements of the subject and predicate device; however, the intended use of the subject and predicate device is the same. In addition, the table reflects differences in technological features of the subject and predicate devices. However, the differences 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 retrieval of human oocytes by follicular aspiration or flushing. 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 time 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
 - 1-cell Mouse Embryo Assay (MEA): ≥ 80% embryos developed to expanded blastocysts at 96 hours following 60 minute exposure to ARTS Media Oocyte Aspiration Medium
 - 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 Oocyte Aspiration is as safe and effective as the predicate device and supports a determination of substantial equivalence.