November 19, 2020

Hamilton Thorne, Inc.
Donald J. Fournier
Director, Regulatory Affairs & QA
100 Cummings Center, Suite 465E
Beverly, MA 01915

Re: K192503
Trade/Device Name: GM501 Wash with Phenol Red and Gentamicin
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: October 22, 2020
Received: October 23, 2020

Dear Donald J. Fournier:

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.
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)*
K192503

Device Name
GM501 Wash with Phenol Red and Gentamicin

Indications for Use *(Describe)*
GM501 Wash with Phenol Red and Gentamicin is intended for in vitro procedures involving handling and micromanipulation of human oocytes and embryos outside of a CO2 incubator. Indications include oocyte and embryo washing (e.g. after oocyte aspiration, after hyaluronidase treatment to remove cumulus cells, before and after cryopreservation, and before embryo transfer) and micromanipulation procedures (e.g. assisted hatching). GM501 Wash with Phenol Red and Gentamicin is not intended for use in transferring embryos into the uterine cavity.

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 – K192503

GM501 Wash with Phenol Red and Gentamicin

Submitter: Hamilton Thorne, Inc.
100 Cummings Center, Suite 465E
Beverly, MA 01915
Tel: (978) 921-2050
Fax: (978) 921-0250

Contact Person: Donald Fournier
Director, Regulatory Affairs & Quality Assurance
100 Cummings Center, Suite 465E
Beverly MA 01915
Tel: (978) 921-2050 Ext. 1726
Fax: (978) 921-0250
dfournier@hamiltonthorne.com

Date Prepared: November 18, 2020

Trade Name: GM501 Wash with Phenol Red and Gentamicin
Common Name: Assisted Reproduction Medium
Regulation Name: Reproductive Media and Supplements
Regulation Number: 21 CFR 884.6180
Product Code: MQL (Media, Reproductive)
Regulatory Class: Class II

Predicate Device: K190383 – GM501 Wash

The predicate device has not been subject to a design-related recall.

Device Description:

GM501 Wash with Phenol Red and Gentamicin is a ready-to-use solution providing supporting conditions for human oocytes and embryos during in vitro Assisted Reproduction Technology (ART) procedures taking place outside of a CO_2 incubator, including washing and micromanipulation procedures. GM501 Wash is aseptically filled into sterilized bottles (20 and 50 ml) and has a six-month shelf-life when stored as recommended. This product can also be used for up to seven days after bottle opening.

GM501 Wash with Phenol Red and Gentamicin is identical to the predicate GM501 Wash with the exception of the addition of gentamicin sulfate (10 mg/liter) and phenol red (3 mg/liter).

Indications for Use Statement:

GM501 Wash with Phenol Red and Gentamicin is intended for in vitro procedures involving handling and micromanipulation of human oocytes and embryos outside of a

CO_2 incubator. Indications include oocyte and embryo washing (e.g. after oocyte aspiration, after hyaluronidase treatment to remove cumulus cells, before and after cryopreservation, and before embryo transfer) and micromanipulation procedures (e.g. assisted hatching). GM501 Wash with Phenol Red and Gentamicin is not intended for use in transferring embryos into the uterine cavity.

Comparison to Predicate:

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

Parameter	**Subject Device GM501 Wash with Phenol Red and Gentamicin K192503**	**Predicate Device GM501 Wash K190383**	**Comparison**
Indications for Use	GM501 Wash with Phenol Red and Gentamicin is intended for in vitro procedures involving handling and micromanipulation of human oocytes and embryos outside of a CO_2 incubator. Indications include oocyte and embryo washing (e.g. after oocyte aspiration, after hyaluronidase treatment to remove cumulus cells, before and after cryopreservation, and before embryo transfer) and micromanipulation procedures (e.g. assisted hatching). GM501 Wash with Phenol Red and Gentamicin is not intended for use in transferring embryos into the uterine cavity.	GM501 Wash is intended for in vitro procedures involving handling and micromanipulation of human oocytes and embryos outside of a CO_2 incubator. Indications include oocyte and embryo washing (e.g. after oocyte aspiration, after hyaluronidase treatment to remove cumulus cells, before and after cryopreservation, and before embryo transfer) and micromanipulation procedures (e.g. assisted hatching). GM501 Wash is not intended for use in transferring embryos into the uterine cavity.	Same
Formulation	Sodium chloride Potassium chloride Glucose Potassium Phosphate Magnesium Sulfate Sodium lactate Sodium hydrogen carbonate Calcium chloride Sodium pyruvate EDTA Amino acids HEPES HSA Water Gentamicin sulfate Phenol red	Sodium chloride Potassium chloride Glucose Potassium Phosphate Magnesium Sulfate Sodium lactate Sodium hydrogen carbonate Calcium chloride Sodium pyruvate EDTA Amino acids HEPES HSA Water	Different – the subject device includes phenol red and gentamicin that are not present in the predicate device formulation. These formulation differences do not raise different questions of safety and effectiveness.
Sterilization	Sterilized by sterile filtration	Sterilized by sterile filtration	Same
Endotoxins	< 0.25 LAL, EU/ml	< 0.25 LAL, EU/ml	Same

Osmolality (mOsm/Kg)	270-290	270-290	Same
pH	7.2-7.5	7.2-7.5	Same
1-Cell MEA	≥ 80% blastocyst at 96h after 1h exposure to GM501 Wash with Phenol Red and Gentamicin	≥ 80% blastocyst at 96h after 1h exposure to GM501 Wash	Same
Shelf-life	6 months	6 months	Same

The subject media product is modification to the predicate device. The two media products have the same specifications (endotoxin, MEA, pH, and osmolality), shelf-life, and sterilization methods. However, differences exist in media formulation. As discussed in the table above, these differences do not raise different questions of safety and effectiveness as compared to the predicate device and can be assessed through performance data.

Summary of Non-Clinical Performance Testing:
The subject device is identical to the predicate device, with the exception that gentamicin sulfate and phenol red have been added to the subject device. Based on the risk analysis, shelf-life and use-life after bottle opening of the subject device was conducted to support the change in formulation. All other testing to support this device relies on testing included in the predicate submission (K190383) and in K192644 for GM501 SpermActive which is identical in formulation to the subject device, but has a different indications for use for handling and preparation of sperm. A summary of the shelf-life and use-life testing conducted to support this change is shown below:

- Shelf-life testing was conducted to support the six-month shelf-life (MEA, sterility, pH, osmolality, and endotoxins)

- Stability testing after bottle opening at the end of the shelf-life period was conducted to ensure that device specifications are met seven days after opening and simulated use of bottles (MEA, sterility, pH, osmolality, and endotoxins)

Conclusion:

The subject and predicate devices have the same intended use and comparable technological characteristics. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.