September 5, 2019

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

Re: K190383
Trade/Device Name: GM501 Wash
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: July 26, 2019
Received: August 1, 2019

Dear Donald 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
Sharon M. Andrews
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)*
K190383

Device Name
GM501 Wash

Indications for Use *(Describe)*
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.

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

K190383 - GM501 Wash

Submitter: Hamilton Thorne, Inc.
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Date Prepared: August 29, 2019

Trade Name: GM501 Wash

Common Name: Reproductive Media

Regulation Name: Reproductive Media and Supplements
Regulation Number: 21 CFR 884.6180
Product Code: MQL (Media, Reproductive)
Regulatory Class: Class II

Predicate Device: LifeGlobal Group, LLC - Global Total w/HEPES w/HSA (K142991). The predicate device has not been subject to a design-related recall.

Device Description:

GM501 Wash 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, 50 and 500 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.

Indications for Use:

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.

Substantial Equivalence Comparison:

Parameter	K181004 Subject Device	K142991 Predicate Device LifeGlobal Global Total w/HEPES w/HSA	Comments
Indications for Use	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.	Oocyte and embryo washing, manipulation, fertilization by intracytoplasmic sperm injection (ICSI), embryo transfer.	**Different:** Both devices are indicated for washing, handling, and manipulation of oocytes and embryos. The predicate device has additional uses beyond the subject device including sperm washing, ICSI, and embryo transfer. These differences do not represent a different intended use, but rather a more limited use for the subject device.
Device Materials	Sodium chloride Potassium chloride Glucose Potassium Phosphate Magnesium Sulfate Sodium lactate Sodium hydrogen carbonate Calcium chloride Sodium pyruvate EDTA Amino acids HEPES HSA Water	Sodium chloride Potassium chloride Glucose Potassium Phosphate Magnesium Sulfate Sodium bicarbonate Sodium lactate Calcium chloride Sodium pyruvate EDTA Amino acids HEPES HSA Phenol red Gentamicin sulfate Water	**Different –** The formulas of the subject and predicate media are not the same. Differences in media product formulations do not raise different questions of safety and effectiveness (S&E).
Sterilization	Aseptic filtration, no growth	Aseptic filtration	**Same**
MEA	1-Cell: ≥80% blastocysts at 96h following a 1h exposure to GM501 Wash	1-Cell: ≥80% blastocysts at 96h	**Different –** Mouse embryos are exposed to the subject medium for one hour as compared to 96 hours for the predicate. Differences in exposure times do not

			raise different questions of S&E.
Endotoxin	<0.25 EU/ml	<0.5 EU/ml	**Different –** The subject device has a lower endotoxin level, which does not raise different questions of S&E.
Osmolality (mOsm/Kg)	270-290	260-270	**Similar**
pH	7.2-7.5	7.2-7.4	**Similar**
Shelf-Life	6 Months	10 Weeks	**Different –** Differences in shelf-life do not raise different questions of S&E.

As noted above, the subject and predicate media products have the same intended use for oocytes and embryos (i.e., short term use in handling, washing, and manipulation procedures outside of an incubator), with the exception of embryo transfer procedures, which represents a more limited indications for use for the subject device as compared to the predicate.

In addition, the two media products have similarities in specifications (pH, osmolality, sterility, etc.) and sterilization methods. However, differences exist in media formulation, endotoxin and MEA specifications, and shelf-life duration for the different media products. 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 on Non-Clinical Performance Testing:

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

- pH testing (acceptance criterion: 7.2-7.5)
- Osmolality testing (acceptance criterion: 270-290 mOsm/kg)
- Aseptic filling validation per ANSI/AAMI/ISO 13408-1:2008(R)2011, ANSI/AAMI/ISO 13408-2:2003(R)2013, and the FDA's "Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice."
- Sterility testing per USP <71> (acceptance criterion: no growth)
- Bacterial endotoxins testing per USP <85> (acceptance criterion: <0.25 EU/ml)
- Mouse Embryo Assay (MEA) using established protocol:

  One-cell mouse embryos were exposed to GM501 Wash for one hour to represent the worst-case exposure for this short-term use medium. The embryos were transferred to culture medium and cultured at 37°C in an atmosphere containing 5% CO2. The percentage of embryos developed to the blastocyst stage within 96 hours were assessed in comparison with the control group. The acceptance specification is "≥80% blastocysts at 96h following a 1h exposure to GM501 Wash."

- Shelf-life testing was conducted to ensure that device specifications for the following parameters are met at time zero and at the end of shelf-life (6 months): pH, osmolality, sterility, 1-cell MEA, and endotoxin

- Stability testing after bottle opening was conducted to ensure that device specifications for the following parameters are met seven days after opening of bottles: pH, osmolality, sterility, 1-cell MEA, and endotoxin.

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.