April 23, 2020

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

Re: K192644
Trade/Device Name: GM501 SpermAir and GM501 SpermActive
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: March 18, 2020
Received: March 24, 2020

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,

Monica D. Garcia, Ph.D.
Acting 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)*
K192644

Device Name
GM501 SpermAir and GM501 SpermActive

Indications for Use *(Describe)*
GM501 SpermAir is intended for the handling and preparation of sperm for use in assisted reproduction procedures. GM501 SpermAir is not intended for use in intrauterine insemination procedures.

GM501 SpermActive is intended for the handling and preparation of sperm for use in assisted reproduction procedures. GM501 SpermActive is not intended for use in intrauterine insemination procedures.

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
K192644
GM501 SpermAir and GM501 SpermActive

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Date Prepared: April 22, 2020

Name of Device: GM501 SpermAir and GM501 SpermActive

Common/Usual 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: K190199 – Kitazato Corporation - SepaSperm® Washing Solution. The predicate device has not been subject to a design-related recall.

Device Description:

GM501 SpermAir and GM501 SpermActive are ready-to-use solutions for handling and preparation of sperm cells during assisted reproduction procedures. Both devices are aseptically filled into sterilized bottles and sealed. GM501 SpermAir comes in three volumes: 2 ml, 20 ml, and 50 ml. GM501 SpermActive comes in two volumes: 20 ml and 50 ml. Both media have a six-month shelf-life when stored as recommended and can be used for up to seven days after opening.

Indications for Use Statements:

GM501 SpermAir is intended for the handling and preparation of sperm for use in assisted reproduction procedures. GM501 SpermAir is not intended for use in intrauterine insemination procedures.

GM501 SpermActive is intended for the handling and preparation of sperm for use in assisted reproduction procedures. GM501 SpermActive is not intended for use in

intrauterine insemination procedures.

Substantial Equivalence Comparison:

Parameter	K192644 Subject Device: GM501 SpermAir/SpermActive	K190199 Predicate Device: SepaSperm® Washing Solution	Comparison
Indications for Use	GM501 SpermAir is intended for the handling and preparation of sperm for use in assisted reproduction procedures. GM501 SpermAir is not intended for use in intrauterine insemination procedures. SpermActive is intended for the handling and preparation of sperm for use in assisted reproduction procedures. GM501 SpermActive is not intended for use in intrauterine insemination procedures.	SepaSperm® Washing Solution is used for preparation and washing of sperm for use in assisted reproduction procedures. SepaSperm® Washing Solution is not intended for use in intrauterine insemination procedures.	The indications for use statements are not identical. However, the subject and predicate devices have the same intended use (preparation of sperm for use in assisted reproduction procedures).
Device Materials	Sodium chloride Potassium chloride Glucose Potassium Phosphate Magnesium Sulfate Sodium lactate Sodium hydrogen carbonate Calcium chloride Sodium pyruvate EDTA Amino acids HEPES Human serum albumin Water Gentamicin Phenol Red	Modified-Human Tubal Fluid Medium HEPES Dextran Polyvinylpyrrolidone D-glucose Water Gentamicin (is certain versions)	**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	Aseptic filtration	**Same**
Endotoxins	< 0.25 LAL, EU/ml	< 0.25 LAL, EU/ml	**Same**
Osmolality (mOsm/kg)	270-290	270-300	**Similar**
pH	7.2-7.5	7.2-7.6	**Similar**

Parameter	K192644 Subject Device: GM501 SpermAir/SpermActive	K190199 Predicate Device: SepaSperm® Washing Solution	Comparison
Human Sperm Survival Assay (HSSA)	≥ 80% of control motility at 24h	≥80% of control motility at 24h	**Same**
Shelf-life	6 months	6 months (without gentamicin) 12 months (with gentamicin)	**Different:** The predicate device has a longer shelf life for the version including gentamicin. This difference does not raise new or different questions of S&E.

As noted in the table above, the subject and predicate devices have the same intended use for preparation of sperm for use in assisted reproduction procedures.

In addition, the subject and predicate devices have similarities in specifications (pH, osmolality, endotoxin, and HSSA) and sterilization methods. However, differences exist in media formulation 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)
- Sterility testing per USP <71> (acceptance criterion: no growth)
- Bacterial endotoxins testing per USP <85> (acceptance criterion: <0.25 EU/ml)
- Human Sperm Survival Assay (acceptance criterion: ≥ 80% of control motility at 24h)
- Shelf-life testing was conducted to support the six-month shelf-life (HSSA, sterility, pH, osmolality, and endotoxins)

- Stability testing after bottle opening was conducted to ensure that device specifications are met seven days after opening of bottles (HSSA, sterility, pH, osmolality, and endotoxins)
- Aseptic filling information per ANSI/AAMI/ISO 13408-1:2008(R)2011, ANSI/AAMI/ISO 13408-2:2003(R)2013
- Simulated shipping and distribution testing on device packaging.

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.