September 18, 2019

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

Re: K191552
Trade/Device Name: GM501 Mineral Oil
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: August 22, 2019
Received: August 23, 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 post marketing 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)*
K191552

Device Name
GM501 Mineral Oil

Indications for Use *(Describe)*
GM501 Mineral Oil is intended for use as an overlay for culture of gametes, zygotes, or embryos in Assisted Reproduction Technology (ART) and micro-manipulation 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

K191552 - GM501 Mineral Oil

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Date Prepared: September 12, 2019

Trade Name: GM501 Mineral Oil

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: FertiPro Oil for Tissue Culture (K053494). The predicate device has not been subject to a design-related recall.

Device Description:

GM501 Mineral Oil is light, mineral oil (paraffin oil) which is used to overlay cell culture media during Assisted Reproductive Technology (ART) or In Vitro Fertilization (IVF) procedures. The oil overlay is intended to protect the culture medium from evaporation in the incubator, limiting potential temperature, osmolality and pH changes in the medium.

GM501 Mineral Oil is aseptically filtered and provided in bottles of 100 ml and 500 ml. This product has an 18-month shelf-life when stored as recommended.

The table below lists the key specifications of the device:

Parameter	Specification
Density	0.83-0.86 g/ml
Viscosity	< 30 cP at 30°C
Sterility (USP<71>)	No growth
Endotoxins (LAL, USP<85>)	< 0.10 EU/ml
1-Cell MEA	≥ 80% blastocysts after 120h exposure
Peroxide Value (POV)	< 0.1 mEq/kg

Indications for Use:

GM501 Mineral Oil is intended for use as an overlay for culture of gametes, zygotes, or embryos in Assisted Reproduction Technology (ART) and micro-manipulation procedures.

Substantial Equivalence Comparison:

The indications for use statements for the subject and predicate devices are shown in the table below:

K191552 **Subject Device** **GM501 Mineral Oil**	**K053494** **Predicate Device** **Oil for Tissue Culture**
GM501 Mineral Oil is intended for use as an overlay for culture of gametes, zygotes, or embryos in Assisted Reproduction Technology (ART) and micro-manipulation procedures.	Oil for Tissue Culture is used in covering tissue culture in in-vitro fertilization, embryo culture and micromanipulative procedures such as ICSI and assisted hatching.

The subject and predicate devices have similar indications for use statements, and the same intended use, i.e., overlay of media used in ART procedures.

The technological features of the subject and predicate device are identical (i.e., materials, specifications, and shelf-life). Therefore, there are no technological differences between the subject and predicate devices that raise different questions of safety and effectiveness.

Summary on Non-Clinical Performance Testing:

Performance testing to support the subject device is identical to that provided in support of the predicate device and supports the device specifications shown in the Device Description section of this summary,

device shelf-life, and validation of the sterilization methods.

Conclusion:

The subject and predicate devices have the same intended use and technological characteristics. Therefore, the subject device is substantially equivalent to the predicate device.