



Food and Drug Administration  
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April 21, 2016

KITAZATO BioPharma Co., Ltd.  
% Diane Sudduth  
RA Consultant  
Emergo Global Consulting, LLC  
816 Congress Avenue, Suite 1400  
Austin, TX 78701

Re: K160142  
Trade/Device Name: Mineral Oil  
Regulation Number: 21 CFR§ 884.6180  
Regulation Name: Reproductive Media and Supplements  
Regulatory Class: II  
Product Code: MQL  
Dated: January 20, 2016  
Received: January 21, 2016

Dear Diane Sudduth,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
**Herbert P. Lerner -S**

for Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K160142

Device Name

Mineral Oil

Indications for Use (Describe)

Mineral Oil is used as an overlay for culture of embryos, oocytes, and sperm in assisted reproduction technology (ART) and micromanipulation 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

### MINERAL OIL

### K160142

#### 1. Submission Sponsor

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#### 3. Date Prepared

April 12, 2016

#### 4. Device Identification

Trade/Proprietary Name: Mineral Oil  
Common/Usual Name: Mineral Oil  
Classification Name: Reproductive media and supplements  
Regulation Number: 21 CFR 884.6180  
Product Code: MQL, Reproductive media and supplements  
Device Class: Class II  
Classification Panel: Obstetrics/Gynecology

#### 5. Legally Marketed Predicate Device(s)

Cook, Sydney IVF Culture Oil, K022002

#### 6. Device Description

Mineral Oil is used to cover medium during embryo, oocyte, and sperm culture in assisted reproduction technology (ART) and micro-manipulation procedures. Mineral Oil is recommended for use as an overlay for a small volume of medium to prevent evaporation and to maintain stable osmolality and pH.

The material composition:

High Purity Paraffin Oil comes in two density types:

- Light type has a ratio between 0.8200 to 0.8400 g/mL (15°C) and a viscosity which is between 8.850 to 11.70mm<sup>2</sup>/s (37.78°C)
- Heavy type has a ratio between 0.8500 to 0.8700 g/mL (15°C) and a viscosity which is between 41.90 to 44.10mm<sup>2</sup>/s (37.78°C).

There are two types of products, Mineral Oil – Light and Mineral Oil – Heavy. Two different unit sizes (100mL and 50mL) are available for each type. Mineral oils are colorless, odorless, tasteless, clear oil fluids which do not produce fluorescence.

Both Mineral Oils (Heavy and Light) do not contact the ova or embryo during culture. Mineral Oil is filter sterilized and dispensed into sterile light-resistant glass bottles.

## 7. Indication for Use Statement

Mineral Oil is used as an overlay for culture of embryos, oocytes, and sperm in assisted reproduction technology (ART) and micromanipulation procedures.

## 8. Substantial Equivalence Discussion

The following Table 1 compares the Mineral Oil to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence.

**Table 1 – Comparison of Characteristics**

Manufacturer	Kitazato BioPharma Co., Ltd.	Cook	Significant Differences
Trade Name	Mineral Oil	Sydney IVF Culture Oil	-
510(k) Number	K160142	K022002	-
Product Code	MQL	MQL	Same
Regulation Number	884.6180	884.6180	
Regulation Name	Reproductive media and supplements	Reproductive media and supplements	Same

<b>Clinical</b>			
Indications for Use	Mineral Oil is used as an overlay for culture of embryos, oocytes, and sperm in assisted reproduction technology (ART) and micromanipulation procedures.	The Sydney IVF Culture Oil is intended for use as an oil overlay for culture of gametes, zygotes, or embryos in assisted reproduction technology (ART) and micromanipulation procedures.	Similar
Patient contact	This product does not contact directly with gametes/embryos as it is used as an overlay for culturing in culture media.	This product does not contact directly with gametes/embryos as it is used as an overlay for culturing in culture media.	Same
Used in similar population	The product is used for fertility treatment of humans	The product is used for fertility treatment of humans	Same
<b>Technical</b>			
MEA	≥ 80% (96h Blastocysts)	≥ 80%	Same
Endotoxin	≤ 0.25 EU/mL (USP)	< 0.4 EU/mL	Similar
Sterilization method	Aseptic filtration sterilization	Aseptic filtration sterilization	Same
Storage method	8-30 °C Dark storage Do not freeze	2-8 °C Do not freeze	Similar
Shelf life	12 months	8 weeks	Similar
Content	100 mL 50 mL	200 mL 50 mL	Similar
Composition	Mineral Oil	Mineral Oil	Same

The technological characteristics of Mineral Oil are comparable to the predicate device. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

## 9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of Mineral Oil and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, KITAZATO BIOPHARMA completed a number of non-clinical performance tests as described below:

- Appearance (color): clear, particle free
- Sterility: No microbial growth from sterility testing per USP <71>
- Endotoxin Testing: Endotoxin values conform to the value  $\leq 0.25$  EU/mL
- MEA:  $\geq 80\%$  of 1-cell control embryos develop at 96 hours
- Peroxide value (POV):  $\leq 0.1$  meq/kg
- Readily carbonizable substance test: no discoloration, color of sulfuric acid layer paler than control per USP <271>
- Shelf-life testing

The Mineral Oil meets all the requirements for overall design, and sterilization results confirming that the design output meets the design inputs and specifications for the device.

#### **10. Statement of Substantial Equivalence**

The results of the testing described above provide a reasonable assurance that Mineral Oil is as safe and effective as the predicate device and supports a determination of substantial equivalence.