DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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February 24, 2017

William A. Cook Australia Pty Ltd
Gordana Pozvek, Ph.D.
Senior Regulatory Affairs Specialist
95 Brandl Street
Eight Mile Plains QLD 4113
Australia

Re: K170257
Trade/Device Name: Sydney IVF Culture Oil
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: Class II
Product Code: MQL
Dated: January 24, 2017
Received: January 27, 2017

Dear Dr. Gordana Pozvek:

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,

Charles Viviano -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170257

Device Name
Sydney IVF Culture Oil

Indications for Use *(Describe)*
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 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 - K170257

SUBMITTED BY:

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Date Prepared: February 24, 2017

DEVICE IDENTIFICATION:

Trade Name:	Sydney IVF Culture Oil
Common Name:	IVF Culture Oil
Regulation No:	21 CFR 884.6180, Reproductive Media and Supplements
Regulatory Class:	II
Product Code:	MQL - Media, Reproductive

PREDICATE DEVICE:

Sydney IVF Culture Oil (**K022002)**

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

DEVICE DESCRIPTION:

Sydney IVF Culture Oil is designed to protect gametes and embryos during ART processing by providing a barrier between the embryo culture media and the air, thereby minimizing evaporation, and reducing fluctuations in osmolality. Sydney IVF Culture Oil consists of pharmaceutical grade mineral oil.

Sydney IVF Culture Oil is provided in glass vials (50 ml). This product is a single use, aseptically-filtered device.

INDICATIONS FOR USE:

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.

COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Sydney IVF Culture Oil has the same Indications for Use as the predicate device cleared under K022002. Therefore, the intended use of the subject device is the same as the predicate device.

Sydney IVF Culture Oil has similar technological characteristics to the predicate device. This 510(k) was submitted to expand the shelf-life from 90 days (predicate device shelf-life) to 20 weeks when stored at 2-8ºC. The difference between subject and predicate devices does not impact substantial equivalence, as it does not raise different questions of safety and effectiveness.

PERFORMANCE DATA:

A real-time shelf-life study was conducted to demonstrate that the Sydney IVF Culture Oil met the following specifications at time zero (0) and after 20 weeks of storage at 2 - 8°C:

- Mouse Embryo Assay (MEA): ≥80% 2-cell embryos expanded to blastocysts at 72 hours
- Endotoxin (LAL): <0.4 EU/ml in accordance with USP <85>
- Sterility: No growth in accordance with USP <71>

CONCLUSION:

The results of the testing demonstrate that the Sydney IVF Culture Oil is as safe and effective as the predicate device, and supports a determination of substantial equivalence.