DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 21, 2015

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

Re: K152782
Trade/Device Name: Sydney IVF Sperm Medium, Sydney IVF Sperm Gradient Kit, Sydney IVF Spermient
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: November 24, 2015
Received: November 30, 2015

Dear 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 yours,

Benjamin R. Fisher -S

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)*
K152782

Device Name
Sydney IVF Sperm Medium

Indications for Use *(Describe)*
Sydney IVF Sperm Medium is intended for use during in vitro fertilization procedures to process sperm.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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Indications for Use

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

510(k) Number *(if known)*
K152782

Device Name
Sydney IVF Sperm Gradient Kit

Indications for Use *(Describe)*
Sydney IVF Sperm Gradient Kit is intended for use during in vitro fertilization procedures to separate motile sperm from seminal plasma.

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)

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

510(k) Number *(if known)*
K152782

Device Name
Sydney IVF Spermient

Indications for Use *(Describe)*
Sydney IVF Spermient is intended for use during in vitro fertilization procedures to separate motile sperm from seminal plasma.

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

SUBMITTED BY:

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Date Prepared: September 22, 2015

DEVICE IDENTIFICATION:

Trade Name:	Sydney IVF Sperm Medium (Product code: K-SISM) Sydney IVF Sperm Gradient Kit (Product code: K-SISG) Sydney IVF Spermient (Product code: K-SISP)
Common Name:	Sperm Processing Solutions
Regulation No:	21 CFR 884.6180, Reproductive Media & Supplements
Regulatory Class:	II
Product Code:	MQL - Media, Reproductive

PREDICATE DEVICE:

Cook IVF Sperm Buffer, Cook IVF Sperm Medium, and Cook IVF Sperm Gradient Kit **(K002383),** cleared September 13, 2000.

DEVICE DESCRIPTION:

The Sydney IVF Sperm Medium, Sydney IVF Sperm Gradient Kit and Sydney IVF Spermient are used for processing sperm during *in vitro* fertilization procedures.

Sperm Medium is used to provide a "liquid" and nutritious environment for the sperm to maintain its motility for the "swim up" procedures and the following fertilization process. The medium contains 10 mg/mL Human Serum Albumin (HSA) and 0.01 mg/mL Gentamicin. It is available in 20, 50 or 100 mL vials.

Sydney IVF Sperm Gradient Kit is used to separate sperm based on density, using density gradient solutions. Sperm Gradient Kit contains both 40% and 80% density solutions and is comprised of silane coated silica particles which are diluted in a HEPES buffer. The sperm gradient has the dual purpose of enriching motile sperm populations and removing sperm inhibitory compounds normally present in the ejaculate. It contains 10 mg/mL HSA and 0.01 mg/mL Gentamicin. Sydney IVF Sperm Gradient Kit is available in 20 or 50 mL vials, packaged in a carton box, consisting of one vial filled with the 40% sperm gradient solution, and a second vial filled with the 80% sperm gradient solution.

Sydney IVF Spermient is intended to separate sperm based on density, using density gradient solutions. This is achieved by diluting the Spermient into various concentrations with a HEPES buffered solution. lt contains colloidal silica coated with an inert polymer (silane) and has been formulated to be isotonic. Spermient contains 10 mg/mL HSA and 0.01 mg/mL Gentamicin. It is available in 20 or 100 mL vials.

The Sydney IVF Sperm Medium, Sydney IVF Sperm Gradient Kit and Sydney IVF Spermient are provided in glass vials with Fluorotec® coated rubber stoppers held in place with a tamper evident seal.. These products are single use, sterile (aseptic filtration) devices.

INDICATIONS FOR USE:

Sydney IVF Sperm Medium is intended for use during in vitro fertilization procedures to process sperm.

Sydney IVF Sperm Gradient Kit and Sydney IVF Spermient are intended for use during in vitro fertilization procedures to separate motile sperm from seminal plasma.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The Sydney IVF Sperm Medium, Sydney IVF Sperm Gradient Kit & Sydney IVF Spermient, and the predicate device **(K002383)** have the same fundamental technology and similar technological characteristics including the following:

- Similar chemical formulation
- Similar performance specifications:
  - Osmolality 285 – 295 mOsm/kg
  - Endotoxin < 0.40 EU/mL
  - A Mouse Embryo Assay (MEA) is used to screen the product for embryo toxicity.
- Same method of manufacturing process - aseptic filtration.
- Same packaging – borosilicate type 1 vials with FluroTec coated stopper and tamper evident seals.

The modification that was made to the predicate device was a change in shelf-life from 8 weeks at 2-8ºC (for predicate device) to 20 weeks at 2-8ºC. In addition, minor changes were made to the formulation and specifications.

The technological characteristics of Sydney IVF Sperm Medium, Sperm Gradient Kit & Spermient are comparable to the predicate device.

PERFORMANCE DATA:

The shelf-life of Sydney IVF Sperm Medium, Sperm Gradient Kit and Spermient has been validated in stability studies to 20 weeks at 2 - 8^{o}C. Stability tests included endotoxin, MEA, Human Sperm Survival Assay (HSSA), pH, osmolality, sterility and the concentrations of pyruvate and the HSA by-product ammonia.

CONCLUSION:

The results of the testing provide reasonable assurance that the Sydney IVF Sperm Medium, Sydney IVF Sperm Gradient Kit and Sydney IVF Spermient Kit is as safe and effective as the predicate device and supports a determination of substantial equivalence.