DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 5, 2016

Willian A. Cook Australia Pty Ltd
Gordana Pozvek
Senior Regulatory Affairs Specialist
95 Brandl Street
Brisbane Technology Park, Eight Mile Plains
Brisbane, QLD 4113, Australia

Re: K152682
Trade/Device Name: Sydney IVF Cryopreservation Kit, Sydney IVF Thawing Kit
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: Class II
Product Code: MQL
Dated: April 5, 2016
Received: April 7, 2016

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,

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

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)*

K152682

Device Name
Sydney IVF Cryopreservation Kit

Indications for Use *(Describe)*
Sydney IVF Cryopreservation Kit is intended for use during in vitro fertilization procedures for cryopreservation of 1-cell to 8-cell embryos.

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."

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)*

K152682

Device Name
Sydney IVF Thawing Kit

Indications for Use *(Describe)*
Sydney IVF Thawing Kit is intended for use during in vitro fertilization procedures for thawing of 1-cell to 8-cell embryos.

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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Special 510(k) Summary – K152682

SUBMITTED BY:

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Date Prepared: May 3, 2016

DEVICE IDENTIFICATION:

Trade Name:	Sydney IVF Cryopreservation Kit (K-SICS-5000) & Sydney IVF Thawing Kit (K-SITS-5000)
Common Name:	Cryopreservation & Thawing Kits
Regulation No:	21 CFR 884.6180, Reproductive Media & Supplements
Regulatory Class:	II
Product Code:	MQL - Media, Reproductive

PREDICATE DEVICE:

Cook IVF Cryopreservation Kit & Cook IVF Thaw Kit **(K011157),** cleared May 3, 2001.

DEVICE DESCRIPTION:

The Sydney IVF Cryopreservation and Thawing Kits are intended for cryopreservation and thawing of 1-cell to 8-cell human embryos. The Sydney IVF Cryopreservation and Thawing Kits provide users with the ability to cryopreserve supernumerary embryos created during the *in vitro* fertilization procedure and then to thaw them for use at a future point in time.

The Sydney IVF Cryopreservation Kit consists of three solutions containing increasing concentrations of cryoprotectant (both propanediol and sucrose are used). These buffers were designed to be used sequentially in order to remove water from embryos prior to cryopreservation. The removal of water prevents ice crystal formation inside the embryo thereby limiting damage and improving viability. It contains 12 mg/mL Human Serum

Albumin (HSA) and 0.01mg/mL Gentamicin. Sydney IVF Cryopreservation Kit is designed for use with Sydney IVF Thawing Kit.

The Sydney IVF Thawing Kit consists of four solutions with decreasing concentrations of cryoprotectants (propanediol and sucrose) which are used sequentially throughout the thawing process. It contains 12 mg/mL Human Serum Albumin (HSA) and 0.01mg/mL Gentamicin. It is designed for use with Sydney IVF Cryopreservation Kit.

Sydney IVF Cryopreservation and Thawing Kits are provided in glass vials with Fluorotec® coated rubber stoppers held in place with a tamper evident seal. Sydney IVF Cryopreservation Kit is packaged in a carton box containing 2 x 10mL and 1 x 20mL solutions per kit. The Sydney IVF Thawing Kit is packaged in a carton box containing 4 x 10mL solutions per kit.

INDICATIONS FOR USE:

Sydney IVF Cryopreservation Kit is intended for use during in vitro fertilization procedures for cryopreservation of 1-cell to 8-cell embryos.

Sydney IVF Thawing Kit is intended for use during in vitro fertilization procedures for thawing of 1-cell to 8-cell embryos.

The only differences in the indications for use listed above and that of the predicate device are:

- An update to clarify the intended use of the device as the original statements refers to “zygotes or embryos”, and this has been updated to “1-cell to 8-cell embryos”. The update serves to describe the intended use more accurately than the previous statement. There is no change to the clinical use of the device.

This clarification does not represent a new intended use nor does it pose any safety or effectiveness issues.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The Sydney IVF Cryopreservation Kit & Sydney IVF Thawing Kit and the predicate device **(K011157)** have the same fundamental technology and similar technological characteristics including the following:

- Similar chemical formulation
- Similar performance specifications:
  - pH 7.3 – 7.5
  - 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 6 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 Cryopreservation Kit & Sydney IVF Thawing Kit are comparable to the predicate device.

PERFORMANCE DATA:

The product specifications for the Sydney IVF Cryopreservation Kit & Sydney IVF Thawing Kit and the predicate device are the same regarding sterility, pH, osmolality and endotoxin.

The MEA is used for both the predicate and the proposed device, but the test assay and specification has changed from 1-cell MEA (96hrs) with ≥75% of control that develop to blastocyst (predicate) to 2-cell MEA (72hrs) with ≥80% of control that develop to blastocyst.

Stability & Shelf Life

The shelf-life of Sydney IVF Cryopreservation Kit & Sydney IVF Thawing Kit has been validated in stability studies to 20 weeks at 2 - 8^{o}C. Stability tests included MEA, endotoxin, osmolality, pH, sterility and the concentrations of the amino acid proline and the HSA degradation by-product ammonia.

CONCLUSION:

The results of the testing provide reasonable assurance that the Sydney IVF Cryopreservation Kit & Sydney IVF Thawing Kit is as safe and effective as the predicate device and supports a determination of substantial equivalence.