DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 27, 2016

William A. Cook Australia Pty, Ltd.
Gordana Pozvek
Senior Regulatory Affairs Specialist
95 Brandl Street
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Brisbane QLD 4113, Australia

Re: K153290
Trade/Device Name: Sydney IVF Follicle Flush Buffer, Sydney IVF Fertilization Medium, Sydney IVF Cleavage Medium, Sydney IVF Blastocyst Medium
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: December 21, 2015
Received: December 28, 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)*
K153290

Device Name
Sydney IVF Follicle Flush Buffer, Sydney IVF Fertilization Medium, Sydney IVF Cleavage Medium, Sydney IVF Blastocyst Medium

Indications for Use *(Describe)*

Sydney IVF Follicle Flush Buffer is intended for use during in vitro fertilization procedures for follicle flushing and oocyte collection.

Sydney IVF Fertilization Medium is intended for use during in vitro procedures for insemination and incubation of oocytes.

Sydney IVF Cleavage Medium is intended for use during in vitro fertilization procedures for culture and transfer of cleavage stage embryos.

Sydney IVF Blastocyst Medium is intended for use during in vitro fertilization procedures for extended culture and transfer of 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.

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510(k) Summary

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Date Prepared: November 10, 2015

DEVICE IDENTIFICATION:

Trade Name:	Sydney IVF Follicle Flush Buffer (Product code: K-SIFB) Sydney IVF Fertilization Medium (Product code: K-SIFM) Sydney IVF Cleavage Medium (Product code: K-SICM) Sydney IVF Blastocyst Medium (Product code: K-SIBM)
Common Name:	Egg/Embryo Processing Solutions
Regulation No:	21 CFR 884.6180, Reproductive Media & Supplements
Regulatory Class:	II
Product Code:	MQL - Media, Reproductive

PREDICATE DEVICE:

Cook IVF Follicle Flushing Buffer, Cook IVF Oocyte Wash Buffer, Cook IVF Fertilization Medium, Cook IVF Cleavage Medium and Cook IVF Blastocyst Medium **(K002385),** cleared September 18, 2000.

DEVICE DESCRIPTION:

The Sydney IVF Follicle Flush Buffer, Sydney IVF Fertilization Medium, Sydney IVF Cleavage Medium and Sydney IVF Blastocyst Medium are used for processing eggs and embryos during *in vitro* fertilization procedures.

Sydney IVF Follicle Flush Buffer is used to flush the follicles during oocyte recovery. It contains Gentamicin (0.01mg/mL) and is available in 100 mL vials.

Sydney IVF Fertilization Medium maintains oocytes in a 6% CO_2 environment until insemination and fertilization is complete. Sydney IVF Fertilization Medium contains Humans Serum Albumin (HSA) (5 mg/mL) and Gentamicin (0.01 mg/mL). It is available in 20, 50 or 100 mL vials.

Sydney IVF Cleavage Medium facilitates the first two days of embryonic growth post fertilization. Sydney IVF Cleavage Medium contains HSA (5 mg/mL) and Gentamicin (0.01 mg/mL). It is available in 20, 50 or 100 mL vials.

Once an embryo has reached the Day 3 (eight-cell) stage, it is then transferred into Sydney IVF Blastocyst Medium. This medium has been metabolically balanced to maximize blastocyst development rates and is suitable for blastocyst transfer. Sydney IVF Blastocyst Medium contains HSA (5 mg/mL) and Gentamicin (0.01 mg/mL). It is available in 20 or 50 mL vials.

The Sydney IVF Follicle Flush Buffer, Sydney IVF Fertilization Medium, Sydney IVF Cleavage Medium and Sydney IVF Blastocyst Medium 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 Follicle Flush Buffer is intended for use during in vitro fertilization procedures for follicle flushing and oocyte collection.

Sydney IVF Fertilization Medium is intended for use during in vitro procedures for insemination and incubation of oocytes.

Sydney IVF Cleavage Medium is intended for use during in vitro fertilization procedures for culture and transfer of cleavage stage embryos.

Sydney IVF Blastocyst Medium is intended for use during in vitro fertilization procedures for extended culture and transfer of embryos.

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

- In the indications for use for **Sydney IVF Cleavage Medium** the wording “for culture and transfer of **cleavage stage** embryos” replaces “for culture and transfer of embryos” which is used in the predicate device. This is an update to clarify the purpose of the device. There is no change to the clinical use of the device.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The Sydney IVF Follicle Flush Buffer, Sydney IVF Fertilization Medium, Sydney IVF Cleavage Medium and Sydney IVF Blastocyst Medium and the predicate device **(K002385)**

have the same fundamental technology and similar technological characteristics including the following:

- Similar chemical formulation
- Similar pH and osmolality specifications
- Similar performance specifications:
  - 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 formulations and specifications.

The technological characteristics of Sydney IVF Follicle Flush Buffer, Sydney IVF Fertilization Medium, Sydney IVF Cleavage Medium and Sydney IVF Blastocyst Medium are comparable to the predicate device.

PERFORMANCE DATA:

The shelf-life of Sydney IVF Follicle Flush Buffer, Sydney IVF Fertilization Medium, Sydney IVF Cleavage Medium and Sydney IVF Blastocyst Medium has been validated in stability studies to 20 weeks at 2 - 8^{o}C. Stability tests included endotoxin, MEA, pH, osmolality, sterility and the concentrations of pyruvate, amino acids (proline and lysine), and the HSA by-product ammonia.

CONCLUSION:

The results of the testing provide reasonable assurance that the Sydney IVF Follicle Flush Buffer, Sydney IVF Fertilization Medium, Sydney IVF Cleavage Medium and Sydney IVF Blastocyst Medium is as safe and effective as the predicate device and supports a determination of substantial equivalence.