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 3, 2015

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

Re: K152904
Trade/Device Name: Sydney IVF Embryo Biopsy Medium
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: Class II
Product Code: MQL
Dated: September 29, 2015
Received: October 1, 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)*

K152904

Device Name
Sydney IVF Embryo Biopsy Medium

Indications for Use *(Describe)*
Sydney IVF Embryo Biopsy Medium is intended for use in assisted reproduction technologies to facilitate the aspiration of blastomeres for pre-implantation genetic diagnosis.

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.

WILLIAM A. COOK AUSTRALIA PTY. LTD.
95 BRANDL STREET
BRISBANE TECHNOLOGY PARK, EIGHT MILE PLAINS
BRISBANE, QLD 4113, AUSTRALIA
PHONE: 1800.777.222 FAX: +61.7.3841.1288
WWW.COOKMEDICAL.COM
ABN 79 005 526 723

510(k) Summary

SUBMITTED BY:

William A. Cook Australia Pty Ltd
95 Brandl Street
Eight Mile Plains QLD 4113
Australia

Contact Person: Gordana Pozvek Ph.D.
Tel: +61 (7) 3841 1188
Fax: +61 (7) 3841 3905
E-mail: Gordana.Pozvek@CookMedical.com

Date Prepared: September 29, 2015

DEVICE IDENTIFICATION:

Trade Name: Sydney IVF Embryo Biopsy Medium (Product code: K-SIEB-20)
Common Name: IVF Culture Media
Regulation No: 21 CFR 884.6180, Reproductive Media & Supplements
Regulatory Class: II
Product Code: MQL - Media, Reproductive

PREDICATE DEVICE:

Sydney IVF Embryo Biopsy Medium **(K023850),** cleared January 22, 2003.

DEVICE DESCRIPTION:

Sydney IVF Embryo Biopsy Medium is bicarbonate based, free of calcium and magnesium to facilitate the aspiration of blastomeres for pre-implantation genetic diagnosis of the embryo. Embryos are placed in this medium for approximately five minutes to break down gap junctions between blastomeres. One or two blastomeres are removed, and the embryo is then returned to Cleavage Medium or Blastocyst Medium for further culture.

Sydney IVF Embryo Biopsy Medium contains Human Serum Albumin (5 mg/mL) and Gentamicin (0.01 mg/mL). The device is available as a 20 mL fill only.

The Sydney IVF Embryo Biopsy Medium is 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 Embryo Biopsy Medium is intended for use in assisted reproduction technologies to facilitate the aspiration of blastomeres for pre-implantation genetic diagnosis.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Sydney IVF Embryo Biopsy Medium and the predicate device (K023850) 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 Embryo Biopsy Medium are comparable to the predicate device.

PERFORMANCE DATA:

The shelf-life of Sydney IVF Embryo Biopsy 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 proline (amino acid), pyruvate and the HSA by-product ammonia.

CONCLUSION:

The results of the testing provide reasonable assurance that the Sydney IVF Embryo Biopsy Medium is as safe and effective as the predicate device and supports a determination of substantial equivalence.