



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

April 22, 2016

William A. Cook Australia Pty Ltd  
Gordana Pozvek, Ph.D.  
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Australia

Re: K160814  
Trade/Device Name: Sydney IVF Sperm Cryopreservation Buffer  
Regulation Number: 21 CFR§ 884.6180  
Regulation Name: Reproductive media and supplements  
Regulatory Class: II  
Product Code: MQL  
Dated: March 21, 2016  
Received: March 24, 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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  
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Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

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

## Indications for Use

510(k) Number (if known)

K160814

Device Name

Sydney IVF Sperm Cryopreservation Buffer

Indications for Use (Describe)

Sydney IVF Sperm Cryopreservation Buffer is intended for use as a buffer to prevent damage to sperm samples during cryopreservation and thawing.

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:** March 21, 2016

### DEVICE IDENTIFICATION:

**Trade Name:** Sydney IVF Sperm Cryopreservation Buffer (K-SISC-20)  
**Common Name:** Cryopreservation Solution  
**Regulation No:** 21 CFR 884.6180, Reproductive Media & Supplements  
**Regulatory Class:** II  
**Product Code:** MQL - Media, Reproductive

### PREDICATE DEVICE:

Sydney IVF Sperm Cryopreservation Buffer (**K061371**), cleared August 17, 2006.

### DEVICE DESCRIPTION:

Sydney IVF Sperm Cryopreservation Buffer consists of an aqueous solution intended for use as a buffer to prevent damage to sperm samples during cryopreservation and thawing. The IVF technician will use the buffer to cryopreserve washed spermatozoa, including MESA (microsurgical epididymal sperm aspiration) and TESA (testicular sperm extraction) samples. Sydney IVF Sperm Cryopreservation Buffer contains glycerol as a cryoprotectant, and HEPES (4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid) as a buffer. This product is used to cryopreserve washed sperm and store them for future use.

Sydney IVF Sperm Cryopreservation Buffer contains Human Serum Albumin (HSA) (4 mg/mL) and Gentamicin (0.01 mg/mL). The device is available as a 20 mL fill only.

**Premarket Notification Submission - Special 510(k)**  
Sperm Cryopreservation Buffer

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The Sydney IVF Sperm Cryopreservation Buffer is provided in glass vials with Fluorotec<sup>®</sup> 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 Cryopreservation Buffer is intended for use as a buffer to prevent damage to sperm samples during cryopreservation and thawing.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:**

Sydney IVF Sperm Cryopreservation Buffer and the predicate device (K061371) have the same fundamental technology and similar technological characteristics including the following:

- Similar chemical formulation
- Same performance specifications:
  - pH 7.3-7.5
  - Osmolality 1190 - 1210 mOsm/kg
  - Endotoxin < 0.40 EU/mL
  - 2 cell Mouse Embryo Assay (MEA) is used to screen the product for embryo toxicity.
  - Human Sperm Survival Assay (HSSA) used to screen the product for sperm 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 12 weeks at -20°C (for predicate device) to 20 weeks at 2-8°C.

The technological characteristics of Sydney IVF Sperm Cryopreservation Buffer are comparable to the predicate device.

**PERFORMANCE DATA:**

The shelf-life of Sydney IVF Sperm Cryopreservation Buffer has been validated in stability studies to 20 weeks at 2 - 8°C. Stability tests included endotoxin, MEA, HSSA, pH, osmolality, HSA and sterility.

**CONCLUSION:**

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