



Food and Drug Administration
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September 23, 2015

Willam A. Cook Australia Pty Ltd
Gordana Pozvek, Ph.D.
Senior Regulatory Affairs Specialist
95 Brandl Street
Eight Mile Plains, Queensland 4113 AU

Re: K152440

Trade/Device Name: Sydney IVF PVP
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: Class II
Product Code: MQL
Dated: August 24, 2015
Received: August 27, 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

Indications for Use

510(k) Number (if known)

K152440

Device Name

Sydney IVF PVP

Indications for Use (Describe)

Sydney IVF PVP is intended for use as an aid in the immobilization and isolation of individual sperm cells prior to intracytoplasmic sperm injection (ICSI) procedures.

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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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 17, 2015

DEVICE IDENTIFICATION:

Trade Name: Sydney IVF PVP (product code: K-SIPV-200-5)
Common Name: Sperm Immobilization Medium
Regulation No: 21 CFR 884.6180, Reproductive Media & Supplements
Regulatory Class: II
Product Code: MQL - Media, Reproductive

PREDICATE DEVICE:

Sydney IVF PVP (product code: K-SIPV-200) (**K031304**),
Cleared - March 23, 2004.

DEVICE DESCRIPTION:

Sydney IVF PVP is a 10 % polyvinylpyrrolidone solution in a bicarbonate buffered media supplemented with 10 mg/mL Human Serum Albumin (HSA) and 0.01 mg/mL Gentamicin. Sydney IVF PVP is ready to use after equilibration to 37°C and 6% CO₂. It is designed to be used by professionals within Assisted Reproduction. This solution is an aseptically filtered sperm medium containing 10% polyvinylpyrrolidone. The PVP increases the viscosity of the solution to facilitate the capture of motile sperm for intracytoplasmic sperm injection (ICSI) procedures during Assisted Reproduction Techniques (ART) procedures.

Sydney IVF PVP is provided in glass vials with FluroTec coated rubber stoppers held in place with a tamper evident seal. It is available in a 5 pack carton box with each vial containing 200 µL Sydney IVF PVP.

INDICATIONS FOR USE:

Sydney IVF PVP is intended for use as an aid in the immobilization and isolation of individual sperm cells prior to intracytoplasmic sperm injection (ICSI) procedures.

The only difference in the indications for use listed above and that of the predicate device is removal of the statement “*Sydney IVF PVP consists of a sperm medium containing 10% polyvinylpyrrolidone (PVP)*”.

This change does not represent a change in the indications for use.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The Sydney IVF PVP and the predicate device (**K031304**) have the same fundamental technology and similar technological characteristics including the following:

- Similar chemical formulation
- 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 sterilisation – Aseptically filtered.
- 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 months at -20°C (for predicate device) to 20 weeks at 2-8°C. In addition, minor changes were made to the formulation and specifications.

The technological characteristics of Sydney IVF PVP are comparable to the predicate device.

PERFORMANCE DATA:

The shelf-life of Sydney IVF PVP has been validated in stability studies to 20 weeks at 2 - 8°C. Stability tests included endotoxin, MEA, sterility and the concentrations of pyruvate and the HSA degradation by-product ammonia.

CONCLUSION:

The results of the testing demonstrate that the Sydney IVF PVP is as safe and effective as the predicate device and supports a determination of substantial equivalence.