



Food and Drug Administration
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August 15, 2016

William A. Cook Australia PTY. LTD.
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Australia

Re: K153478
Trade/Device Name: Sydney IVF Gamete Buffer
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: July 13 2015
Received: July 15, 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,

Douglas Silverstein -S
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Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
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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)

K153478

Device Name

Sydney IVF Gamete Buffer

Indications for Use (Describe)

Sydney IVF Gamete Buffer is used to physically wash and store gametes in preparation for the fertilization step in the IVF process.

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.

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510(k) Summary – K153478

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Date Prepared: August 11, 2016

DEVICE IDENTIFICATION:

Trade Name: Sydney IVF Gamete Buffer
Model Numbers: K-SIGB-20-AA, K-SIGB-50-AA, K-SIGB-100-AA
Common Name: IVF Media
Regulation No: 21 CFR 884.6180, Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL - Media, Reproductive

PREDICATE DEVICE:

G-IVF™ PLUS (K081116) manufactured by Vitrolife Sweden AB, cleared September 2, 2008.

DEVICE DESCRIPTION:

Sydney IVF Gamete Buffer is a HEPES buffered physiologic solution used to physically wash gametes in preparation for the fertilization step in the IVF process. Sydney IVF Gamete Buffer can be used for both sperm and oocytes. This solution can be used to wash oocytes of excess blood following aspiration and also as a short term storage solution until transfer to a fertilisation medium. Sydney IVF Gamete Buffer is based upon the formulation of a 20 mM HEPES buffered media containing salts, non-essential amino acids, glucose, 10 mg/mL Human Serum Albumin (HSA) and 0.01 mg/mL Gentamicin.

Sydney IVF Gamete Buffer is packaged in 20, 50 or 100 mL borosilicate Type I glass vials with Fluorotec[®] coated rubber stoppers held in place with a tamper evident seal. These products are single use, sterile (aseptic filtration) devices. It has a shelf life of 20 weeks when stored at 2 – 8 °C.

INDICATIONS FOR USE:

Sydney IVF Gamete Buffer is used to physically wash and store gametes in preparation for the fertilization step in the IVF process.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Sydney IVF Gamete Buffer and the predicate (K081116) are based on similar technology, principal of operation and equivalent intended use/indications for use. Both Sydney IVF Gamete Buffer and the predicate are buffered physiological formulations containing HSA, Non-Essential Amino Acids and Gentamicin used to wash and prepare gametes for fertilization during the IVF process.

Sydney IVF Gamete Buffer and the predicate device 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
 - Endotoxin: < 0.40 EU/mL
 - 2-cell Mouse Embryo Assay (MEA) \geq 80% blastocyst at 72 hours
 - Human Sperm Survival Assay (HSSA)
- Same method of manufacturing process - aseptic filtration
- Similar packaging
- Similar shelf life
- Identical storage temperature

Technological characteristics such as formulation, shelf-life, pH, osmolality, MEA, endotoxin, and HSSA specifications of Sydney IVF Gamete Buffer are similar to the predicate device, and differences do not impact substantial equivalence as they do not raise different questions of safety or effectiveness.

PERFORMANCE DATA:

Bench testing of the Sydney IVF Gamete Buffer included pH, osmolality, endotoxin, bioburden, and sterility.

The two-cell MEA and Human Sperm Survival Assay (HSSA) were also conducted. These functional tests provide assurance that the Sydney IVF Gamete Buffer functions in accordance with its intended use with regards to oocyte and sperm wash procedure.

Successful results in these tests provide evidence of reproducible conformance to specifications.

Stability of the device was tested through MEA, Endotoxin, HSSA, Osmolality, pH, sterility, pyruvate, ammonia and amino acid (proline) testing of the product over the proposed shelf life.

CONCLUSION:

The results of the testing provide reasonable assurance that Sydney IVF Gamete Buffer has been designed and tested to assure conformance to the requirements for its intended use, is as safe and effective as the predicate device and supports a determination of substantial equivalence.