K061371

AUG 17 2006

510(k) SUMMARY

Submitted By: Brenda Davis
Regulatory Affairs Technical Writer
Cook Urological Incorporated
1100 West Morgan Street
Spencer, IN 47460
(812) 829-4891 x 7257
28 April 2006

Device:

Trade Name: Sydney IVF Sperm Cryopreservation Buffer

Proposed Classification Name: Reproductive Media and Supplements
21 CFR Part 884.6180 (87MQL)
Class II

Predicate Devices:

Sydney IVF Sperm Cryopreservation Buffer is comparable to predicate devices described by criteria set forth in the final rule [63 FR 48428].

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.

Substantial Equivalence

Sydney IVF Sperm Cryopreservation Buffer is comparable with respect to intended use to the published predicate device description and meets the requirements for 510(k) substantial equivalence.

Test Data

Sydney IVF Sperm Cryopreservation Buffer was subjected to the following tests to assure satisfactory operating performance:

- pH Testing
- Osmolality Testing
- Two-cell Mouse Embryo (MEA) Testing
- Bacterial Endotoxin (LAL) Testing

The Sydney IVF Sperm Cryopreservation Buffer passed the requirements of all tests. This device is similar, with respect to intended use and technological characteristics, to the FDA published predicate device description.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 17 2006

Ms. Brenda Davis
Regulatory Affairs Technical Writer
Cook Urological, Inc.
1100 West Morgan Street
SPENCER IN 47460

Re: K061371
Trade/Device Name: Sydney IVF Sperm Cryopreservation Buffer
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplement
Regulatory Class: II
Product Code: MQL
Dated: May 10, 2006
Received: May 19, 2006

Dear Ms. Davis:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K061371

INDICATIONS FOR USE

510(k) Number (if known): K061371

Device Name: Sydney IVF Sperm Cryopreservation Buffer

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.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061371