

510(k) Summary as Required by Section 807.92(a)

Submitted By: COOK OB/GYN™
Regulatory Affairs
1100 West Morgan Street
Spencer, Indiana, 47460
Telephone: 812-829-6500
Facsimile: 812-829-2022
Contact: Brenda Davis
Date Submitted: April 8, 2003

Names of Device:

Trade Name: Sydney IVF™ PVP
Common/Usual Name: Sperm Immobilization Medium
Classification Name: Reproductive media and supplements
21 CFR, 884.6180 (85MQL)

Predicate Device: 63 FR 48428, September 10, 1998

Device Description:

Sydney IVF™ PVP is an aqueous solution containing 10% polyvinylpyrrolidone (PVP), and is used to reduce the motility of sperm and make it easier to collect them with an ICSI Pipette. Sydney IVF™ PVP is provided in glass vials with FluroTech-coated stoppers available in 200 μ L fill volumes.

Intended Use:

Sydney IVF™ PVP consists of a sperm medium containing 10% polyvinylpyrrolidone (PVP) and is intended for use as an aid in the immobilization and isolation of individual sperm cells prior to intracytoplasmic sperm injection (ICSI) procedures.

Substantial Equivalence:

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

Discussion of Tests and Test Results:

Sydney IVF™ PVP was subjected to testing to assure biocompatibility and satisfactory operating performance. Sydney IVF™ PVP passed the requirements of all tests.

Conclusions Drawn from Tests:

This device is similar, with respect to intended use and technological characteristics, to the FDA published predicate device description.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 2004

Ms. Brenda Davis
Regulatory Affairs/Technical Writer
Cook Ob/Gyn
1100 W. Morgan Street
SPENCER IN 47460-6500

Re: K031304
Trade/Device Name: Sydney IVF™ PVP
Regulation Number: 21 CFR §884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: 85 MQL
Dated: December 23, 2003
Received: December 24, 2003

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 (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); 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.

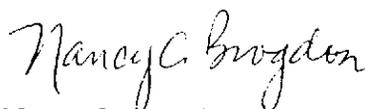
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to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

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K 031304

Device Name: Sydney IVF™ PVP

Indications For Use:

Sydney IVF™ PVP consists of a sperm medium containing 10% Polyvinylpyrrolidone (PVP) and is intended for use as an aid in the immobilization and isolation of individual sperm cells prior to intracytoplasmic sperm injection (ICSI) procedures.

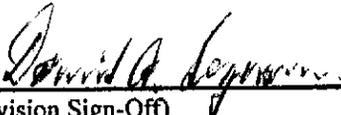
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031304