K023850

9 510(k) Summary

JAN 22 2003

Submitted By: Debbie Schmitt, Regulatory Affairs
COOK OB/GYN™
1100 West Morgan Street
Spencer, Indiana, 47460
812 829-6500

November 18, 2002

Names of Device:

Trade Name:	Sydney IVF Embryo Biopsy Medium
Common/Usual Name:	IVF culture media
Classification Name:	Reproductive media and supplements 21 CFR §884.6180 (87MQL); Class II

Predicate Device: 63 FR 48428, September 10, 1998

Device Description:
Sydney IVF Embryo Biopsy Medium is an aqueous solution containing electrolytes and buffering agents, and is provided in glass vials with silicone rubber stoppers. Sydney IVF Embryo Biopsy Medium will be available in 20 mL fill volumes.

Intended Use:
Sydney IVF Embryo Biopsy Medium is intended for use in assisted reproduction technologies to facilitate the aspiration of blastomeres for pre-implantation genetic diagnosis.

Substantial Equivalence:
Sydney IVF Embryo Biopsy Medium 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 Embryo Biopsy Medium was subjected to testing to assure satisfactory operating parameters. Sydney IVF Embryo Biopsy Medium 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2003

Ms. Debbie Schmitt
Regulatory Affairs Manager
Cook OB/GYN™
1100 W. Morgan Street
SPENCER IN 47460

Re: K023850
Trade/Device Name: Sydney IVF Embryo Biopsy Medium
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: 85 MQL
Dated: November 18, 2002
Received: November 19, 2002

Dear Ms. Schmitt:

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

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

Enclosure

510(k) Number (if known) K023850

Device Name: **Sydney IVF Embryo Biopsy Medium**

Indications For Use: Sydney IVF Embryo Biopsy Medium is intended for use in assisted reproduction technologies to facilitate the aspiration of blastomeres for pre-implantation genetic diagnosis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023850

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)