K983596

FEB 5 1999

510(k) Premarket Notification
Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes, Holding Pipettes, Denuding Pipettes, and Assisted Hatching/Zona Drilling Pipettes
Cook OB/GYN

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:
Debbie Schmitt
Cook OB/GYN
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-6500
October 13, 1998

Device:

Trade Name:	Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes, Holding Pipettes, Denuding Pipettes, and Assisted Hatching/Zona Drilling Pipettes
Proposed Classification Name:	Class II Assisted Reproduction Microtools 85MQH
CFR Reference:	884.6130

Predicate Devices:
Cook OB/GYN understands due to the recent reclassification there are no predicate devices. We have used other devices as well as Cook Australia devices as our predicate to illustrate safety and effectiveness.

The Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes, Holding Pipettes, Denuding Pipettes, and Assisted Hatching/Zona Drilling Pipettes are substantially equivalent to other pipettes in terms of indications for use, design, construction and materials equivalence.

Specifically, these devices are similar to the Intracytoplasmic Micropipet and Holding Micropipet manufactured by Humagen Fertility Diagnostics, Inc., 2345 Hunter's Way (No. 2), Charlottesville, VA 22901-7928, the Laboratory Micropipette Art. No. 33311 and Laboratory Micropipette Art. No. 22218 manufactured by SWEMED LAB International AB, Box 4014 S-421 04 V. Frolunda, Sweden and the (ICSI) pipettes, holding
pipettes, denuding pipettes and assisted hatching/zona drilling pipettes manufactured and distributed in Europe by Cook Australia, 12 Electronics Street, Brisbane Industrial Park, Eight Miles Plains, Queensland, 4113, Australia.

Device Description:
The Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes are used for the intracytoplasmic single sperm injection of oocytes, the Holding Pipettes are used to hold the oocyte in position with the application of vacuum during single sperm injection with the micro-injection pipette, the Denuding Pipettes are used to remove cumulus cell layers, and the Assisted Hatching/Zona Drilling Pipettes are used to make a hole in the zona pellucida to enable blastomere removal or embryo assisted hatching. These devices are manufactured entirely from borosilicate glass. Mouse Embryo Toxicity testing has been performed on the borosilicate glass. Results show the material meets the requirements of these tests.

Substantial Equivalence:
This device will be manufactured according to specified process controls and a Quality Assurance Program. Being similar with respect to indications for use, materials and physical construction to predicate devices, these devices meet the requirements for section 510(k) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 5 1999

Ms. Debbie Schmitt
Regulatory Affairs Manager
Cook Ob/Gyn®
1100 West Morgan
Spencer, IN 47460

Re: K983596
Intracytoplasmic Sperm Injection
Micro-Injection Pipettes, Holding Pipettes
and Assisted Hatching/Zona Drilling Pipettes
Dated: December 23, 1998
Received: December 28, 1998
Regulatory Class: II
21 CFR 884.6130/Procode: 85 MQH

Dear Ms. Schmitt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT K983596

510(k) Number (if known): Not yet assigned

Device Name: Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes
Holding Pipettes
Denuding Pipettes
Assisted Hatching/Zona Drilling Pipettes

Indications for Use: The Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes are used for the intracytoplasmic single sperm injection of oocytes. The Holding Pipettes are used to hold the oocyte in position with the application of vacuum. The Denuding Pipettes are used to remove the cumulus cell layers. The Assisted Hatching/Zona Drilling Pipettes are used to make a hole in the zona pellucida to enable blastomere removal or embryo assisted hatching.

(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, ENT,
and Radiological Devices
510(k) Number K983596/S002

Prescription Use ✓ OR Over-The-Counter Use____