DEC 16 1998

9 510(K) SUMMARY K983609

Submitted By: Brenda Davis
Regulatory Affairs
COOK OB/GYN™
1100 West Morgan Street
Spencer, Indiana, 47460.

October 13, 1998

Names of Device:

Trade Name:	COOK Test Tube Heater
Common/Usual Name:	IVF Test Tube Heater
Proposed Classification Name:	Assisted reproduction accessory - Collection tube warmer 21 CFR §884.6120

Predicate Device: 63 FR 48428, September 10, 1998

Device Description:
The COOK Test Tube Heater is an electronically controlled heating unit that holds collection test tubes and their contents during oocyte recovery. The unit is designed to accept up to six Falcon® 2001 Series 10 mL test tubes.

Intended Use:
The COOK Test Tube Heater is intended to be used to maintain the temperature of egg (oocyte) collection tubes at or near body temperature.

Substantial Equivalence:
The COOK Test Tube Heater is comparable with respect to intended use to the FDA published predicate device description and meets the requirements for 510(k) substantial equivalence.

Discussion of Tests and Test Results:
The COOK Test Tube Heater was subjected to testing to assure satisfactory operating performance. The COOK Test Tube Heater 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

DEC 16 1998

Ms. Brenda Davis
Regulatory Affairs
Cook Ob/Gyn®
1100 West Morgan Street
Spencer, IN 47460

Re: K983609
Cook Test Tube Heater
Dated: October 13, 1998
Received: October 14, 1998
Regulatory Class: II
21 CFR 884.6120/Procode: 85 MQG

Dear Ms. Davis:

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

510(k) Number (if known): K983609

Device Name: COOK Test Tube Heater

Indications For Use:

The COOK Test Tube Heater is intended to be used to maintain the temperature of egg (oocyte) collection tubes at or near body temperature. The unit is designed to accept up to six Falcon® 2001 Series 10 mL test tubes.

(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, ENT, and Radiological Devices
510(k) Number K983609

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