K983595

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

Brenda Davis
Cook OB/GYN
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-4891
October 13, 1998

Device

Trade Name:	Transmyometrial Embryo Transfer Set
Proposed Classification Name:	Assisted Reproduction Catheters Class II 85 MQF

Predicate Devices:

Cook OB/GYN understands due to the recent reclassification there are no predicate devices.
We have used Cook Australia products as our predicate to illustrate safety and effectiveness.
The Transmyometrial Embryo Transfer Set is substantially equivalent to other Transmyometrial Embryo Transfer Sets in terms of indications for use, design, construction and materials equivalence. Specifically, this device is similar to the Intra-Endometrial Embryo Transfer Set manufactured by Cook Australia.

Device Description:

The Transmyometrial Embryo Transfer Set is used for transferring IVF embryo(s) into the endometrial cavity through the myometrium. The Transmyometrial Embryo Transfer Set should not be used on a patient with an active vaginal or intrauterine infection, a sexually transmitted disease, a recent uterine perforation, cervical stenosis or other cervical abnormalities which would preclude embryo transfer, a recent cesarean section, a recent pregnancy (or is currently pregnant), or if the patient currently has an intrauterine device. The materials used in this device are TFE and 300 Series Stainless Steel.
Both materials are widely used in the medical field and biocompatibility is assured.

Substantial Equivalence:

This device will be manufactured according to specified controls and a Quality Assurance Program. This device will undergo packaging similar to the devices currently marketed and distributed by Cook OB/GYN. Being similar with respect to indications for use, materials and physical construction to predicate devices, this device meets the requirements for this section 510(k) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 1999

Brenda Davis
Regulatory Affairs
Cook Ob/Gyn
1100 West Morgan Street
Spencer, Indiana 47460

Re: K983595
Transmyometrial Embryo Transfer Set
Dated: December 1, 1998
Received: December 4, 1998
Regulatory Class: II
21 CFR 884.6110/Procode: 85 MQF

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

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K983595

Device Name: Transmyometrial Embryo Transfer Sets

Indications for Use: The Transmyometrial Embryo Transfer Sets are used for transferring IVF embryo (s) into the endometrial cavity through the myometrium. These devices are sterile and intended for one time use. The Transmyometerial Embryo Transfer Set should not be used on a patient with an active vaginal or intrauterine infection, a sexually transmitted disease, a recent uterine perforation. cervical stenosis or other cervical abnormalities which would preclude embryo transfer, a recent cesarean section, a recent pregnancy (or is currently pregnant), or if a patient currently has an intrauterine device.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983595/S001