

K983587

## I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

### Submitted By:

Brenda Davis  
Cook OB/GYN  
1100 West Morgan Street  
Spencer, Indiana 47460  
(812) 829-6500  
October 13, 1998

### Device

Trade Name:	Hysteroscopic GIFT Catheter Sets
Proposed Classification Name:	Assisted Reproduction Catheters Class II 85 MQF

### Predicate Devices:

Cook OB/GYN understands due to the recent reclassification there are not predicate devices. We have used Cook Australia products as our predicate to illustrate safety and effectiveness. The Hysteroscopic GIFT Catheter Sets are substantially equivalent to other GIFT catheters in terms of indications for use, design, construction and materials equivalence. Specifically, these catheters are similar to the Lee Hysteroscopic Intrafallopian Transfer Catheter manufactured by Cook Australia.

### Device Description:

The Hysteroscopic GIFT Catheter Sets are used to transfer gametes directly into the fallopian tube. The materials used in these devices are TFE and Stainless Steel. Materials used in these sets are widely used in the medical field and biocompatibility is assured.

### Substantial Equivalence:

These sets will be manufactured according to specified process controls and a Quality Assurance Program. These sets 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, these sets meet the requirements for section 510(k) substantial equivalence.



DEC 16 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Ms. Brenda Davis  
Regulatory Affairs Technical Writer  
Cook Ob/Gyn®  
1100 West Morgan Street  
Spencer, Indiana 47460Re: K983587  
Hysteroscopic GIFT Catheter Sets  
Dated: October 13, 1998  
Received: October 13, 1998  
Regulatory Class: II  
21 CFR 884.6110/Procode:85 MQF

Dear Ms. Davis:

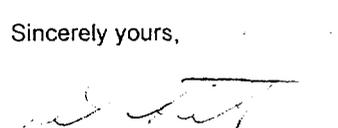
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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

K 983587

**PREMARKET NOTIFICATION**  
**INDICATIONS FOR USE STATEMENT**

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

**Device Name:** Hysteroscopic GIFT Catheter Sets

**Indications for Use:** The Hysteroscopic GIFT Catheter Sets are used to transfer gametes directly into the fallopian tube via hysteroscopic guidance. These catheters and sets are intended for one time use and will be marketed sterile.

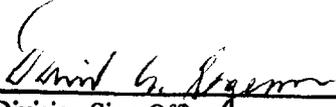
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

  
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(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K 983587