MAR - 1 2000

K994417

510(k) Premarket Notification
Ovum Pick-Up Aspiration Needles with AQ
Cook OB/GYN

I. 510(k) SUMMARY

Submitted By:

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

Device	85MQE 79GAA
Trade Name:	Ovum Pick-Up Aspiration Needles with AQ Coating Aspiration Needles with AQ Coating
CFR Reference:	884.6100 878.4800
Proposed Classification Name:	Ovum Pick-Up Aspiration Needles with AQ Coating Aspiration Needles with AQ Coating

Predicate Devices:

The Ovum Pick-Up Aspiration Needles with AQ Coating and the Aspiraiton Needles with AQ Coating are substantially equivalent to predicate devices in terms of indications for use, design, and materials of construction. Predicate devices include the Cook OB/GYN Ovum Pick-Up Needles and the Aspiration Needles. The predicate AQ devices include the Hydrophilic Stents, Hydrophilic Dilators, and Hydrophilic catheters manufactured and marketed by Cook OB/GYN (Cook Urological).

Device Description:

The Ovum Pick-Up Aspiration Needles with AQ coating is used for transvaginal ultrasound or laparoscopic aspiration/flushing of oocytes from ovarian follicles. The Aspiration Needles with AQ coating are used for general aspiration and irrigation.

Substantial Equivalence:

These devices 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, 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

MAR - 1 2000

Ms. Debbie Schmitt
Regulatory Affairs Manager
COOK® Urological
1100 W. Morgan Street
Spencer, IN 47460

Re: K994417
Ovum Pick-Up Aspiration Needles with AQ (Hydrophilic) Coating and Aspiration Needles with AQ (Hydrophilic) Coating
Dated: December 23, 1999
Received: December 29, 1999
Regulatory Class: II
21 CFR §884.6100/Procode: 85 MQE

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) 594-4591. 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 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K994417

Device Name: Aspiration Needles/Ovum Pick-Up Aspiration Needles with AQ Coating

Indications for Use: The Aspiration/Ovum Pick-Up Aspiration Needles with AQ Coating are used for general irrigation/aspiration and flushing of oocytes from ovarian follicles.

(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 K994417