SEP 27 1993

K932114

I. 510(K) SUMMARY

Submitted By:

Tammy Bacon
COOK OB/GYN
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-4891
April 29, 1993

Device:

Trade Name: Tubal Lumen Support
Common/Usual Name: Duct Probe, Tissue Support, Rod
Proposed Classification: Obstetric-Gynecologic General Manual Instrument

Predicate Devices:

The Tubal Lumen Support is polyurethane flexible rod which is similar to preamendment devices in terms of indications for use and design.

Device Description:

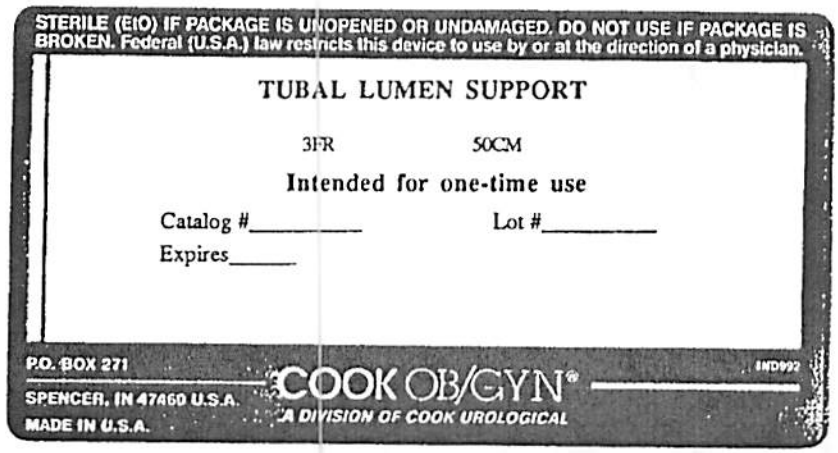
The Tubal Lumen Support is used for maintaining patency of and providing support to the fallopian tube during an anastomosis procedure. The device is intended for one-time use. The construction materials comprising the Tubal Lumen Support are biocompatible, having an established history of use in medical products.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program. The device will undergo packaging and sterilization procedures similar to devices currently marketed and distributed by COOK OB/GYN. This device is similar with respect to indications for use and design to preamendment devices in terms of section 510(k) substantial equivalency.

EXHIBIT I

DEVICE LABELING


STERILE (EtO) IF PACKAGE IS UNOPENED OR UNDAMAGED. DO NOT USE IF PACKAGE IS BROKEN. Federal (U.S.A.) law restricts this device to use by or at the direction of a physician.
TUBAL LUMEN SUPPORT
3FR
50CM
Intended for one-time use
Catalog #_____
Lot #_____
Expires_____
P.O. BOX 271
SPENCER, IN 47460 U.S.A.
MADE IN U.S.A.
COOK OB/GYN®
A DIVISION OF COOK UROLOGICAL

DRAFT LABELING

TUBAL LUMEN SUPPORT
SUGGESTED INSTRUCTIONS FOR USE

1. During surgery, isolate and remove the occluded segment of the fallopian tube using microsurgical techniques.

2. Pass one end of the Tubal Lumen Support into the proximal (uterine) segment of the fallopian tube, advancing it toward the uterus.

3. Pass the other end of the Tubal Lumen Support into the distal segment of the fallopian tube and on through the fimbriated end.

4. Join the cut distal and proximal ends of the fallopian tube over the Tubal Lumen Support, suturing the ends to form the anastomosis.

5. Upon completion of the anastomosis, remove the Tubal Lumen Support by gently withdrawing it through the fimbriated end of the fallopian tube.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

SEP 27 1994

Ms. Tammy Bacon
Regulatory Affairs
Cook OB/GYN®
1100 West Morgan Street
P.O. Box 271
Spencer, Indiana 47460

Re: K932114/B
Tubal Lumen Support
Dated: August 23, 1994
Received: August 24, 1994
Regulatory Class: II
21 CFR 884.3650/Procode: 85 HFJ

Dear Ms. Bacon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined the device is substantially equivalent to 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health