3/25/99

K990072

I. 510(k) SUMMARY

Submitted By:

Debbie Schmitt
Cook Urological
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-4891
Date: January 8, 1999

Device

Trade Name:	Pursuit Balloon Dilation Catheter
Proposed Classification Name:	Dilator, Catheter, Ureteral

Predicate Devices:

The Pursuit Balloon Dilation Catheter is substantially equivalent to predicate devices in terms of indications for use and design. Predicate devices include Balloon Dilation Catheters manufactured by Bard and High Pressure Ureteral Dilatation Balloon Catheter manufactured by Microvasive also a variety of Balloon Dilation Catheters from Cook Urological, Inc.

Device Description:

The Pursuit Balloon Dilation Catheter is used for the ureteral dilation prior to ureteral stone manipulation or ureteroscopy, and dilating the intramural ureter. The materials used to construct the balloon is nylon and polyethylene. The Pursuit Balloon Dilation Catheter will be offered in a 5FR diameter and 40cm to 100cm long catheter with a 5mm to 10mm x 4cm to 10cm balloon.

Substantial Equivalence:

The device will be manufactured by Cook Incorporated according to specified process controls and Quality Assurance Program. The device will undergo packaging and sterilization procedures similar to devices currently marketed and distributed by Cook Urological. Being similar with respect to indications for use, materials and physical construction to predicate devices, this device meets 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 25 1999

Ms. Debbie Schmitt
Regulatory Affairs Manager
Cook Urological, Inc.
1100 West Morgan Street
Spencer, IN 47460

Re: K990072
Pursuit Balloon Ureteral Dilation Catheter
Dated: March 16, 1999
Received: March 17, 1999
Regulatory Class: II
21 CFR 876.5470/Procode: 78 EZN

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) 594-4613. 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): Unknown at this time K990072

Device Name: **Pursuit Balloon Dilation Catheter**

Indications for Use: The device is intended for ureteral dilation prior to ureteral stone manipulation, ureteroscopy, and dilating the intramural ureter.

(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 K990072