

OCT 10 1997

L 510(k) SUMMARY

Submitted By:

Tammy Bacon
Cook Urological
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-4891
August 8, 1997

Device

Trade Name: Insulator Wire Guide
Proposed Classification Name: Electrosurgical Cutting & Coagulation Device & Accessories

Predicate Devices:

The Insulator Wire Guide is substantially equivalent to predicate insulated wire guides in terms of indications for use, design, construction and materials equivalence. Specifically, this device is similar to the Protector Plus manufactured by Wilson-Cook Medical Inc.

Device Description:

The Insulator Wire Guide is used either inside or alongside a urological catheter or electrosurgical catheter for catheter positioning or exchange in the urinary tract. When used with a electrosurgical catheter, the Insulator Wire Guide will decrease the risk of alternate site burns to the patient. The primary material used in this device is TFE. TFE is widely used in the medical field and biocompatibility is assured. Performance testing was performed showing the device to meet requirements for a safe and effective insulated wire guide.

Substantial Equivalence:

This device will be manufactured according to specified process controls and a Quality Assurance Program. This device will undergo packaging 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tammy Bacon
Regulatory Affairs Technical Writer
Cook Urological, Inc.
1100 West Morgan Street
Spencer, Indiana 47460

Re: K972977
Insulator Wire Guide
Dated: August 8, 1997
Received: August 11, 1997
Regulatory class: II
21 CFR §876.5130/Product code: 78 KNY

OCT 10 1997

Dear Ms. Bacon:

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 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 (Pre-market 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 requirement, 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/dsmmain.html>.

Sincerely yours,

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

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

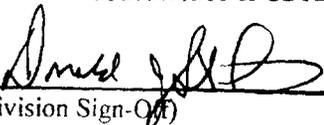
510(k) Number (if known): Not yet assigned

Device Name: Insulator Wire Guide

Indications for Use: The Insulator Wire Guide will be used either inside or alongside a urological catheter or electrosurgical catheter for catheter positioning or exchange in the urinary tract. When used with an electrosurgical catheter, the Insulator Wire Guide will decrease the risk of alternate site burns to the patient. This device is intended for one-time use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal, EN
and Radiological Devices

510(k) Number K972977

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use