RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK NEEDLE KNIFE PAPILLOTOME

J. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

AUG 15 1997

Submitted By:
Wilson-Cook Medical Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105

Device Description:
The Wilson-Cook Needle Knife Papillotome consists of a single lumen tubing, 23 gauge needle, and a papillotome handle. This device is designed for insertion through the accessory channel of an endoscope. The catheter is advanced through the accessory channel positioning the needle knife near the papillary orifice. The device is connected to an electrocautery unit via an active cord. The current from the electrocautery unit is passed through the cutting wire to the distal end of the papillotome thus allowing the needle knife to make small incisions in the papilla. Once the appropriate incision has been made the needle knife may be retracted allowing cannulation of the biliary tree.

Trade Name:	Wilson-Cook Needle Knife Papillotome
Common/Usual Name:	Needle Knife Papillotome
Classification Name:	Device, Electrosurgical, Cutting and Coagulation & Accessories; 79 GEI
Classification:	FDA has classified similar devices as Class II, per 21 CFR § 878.4400. This device falls within the purview of the Gastroenterology and Urology Devices Panel.
Performance Standards:	To the best of our knowledge, performance standards for this device do not exist.
Sterility:	Validated EO cycle, following the AAMI Overkill Method to SAL 10^{-6}.
Intended Use:	The Wilson-Cook Needle Knife Papillotome is used for accessing the common bile duct when standard cannulation methods have been exhausted.

Predicate Device:

PREDICATE DEVICE	MANUFACTURER	DOCUMENT CONTROL NUMBER
Needle Knife Papillotome	Endovations, Inc.	K934315

K 972674 97287

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK NEEDLE KNIFE PAPILLOTOME

J. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

DEVICE CHARACTERISTIC	WILSON-COOK NEEDLE KNIFE PAPILLOTOME [Subject of 510(K)]	ENDOVATIONS, INC. .035" PRE-CUT NEEDLE KNIFE (K934315)
Intended Use	Accessing the common bile duct when standard cannulation methods have been exhausted.	Accessing the common bile duct when standard cannulation methods have been exhausted.
Introducer Catheter/Sheath	Polytetrafluoroethylene	Polytetrafluoroethylene
Handle Style	3-Ring	3-Ring
Needle	304 Stainless Steel	304 Stainless Steel
Needle Gauge	23 GA	23 GA
Needle Extension	4 mm	4 mm
Outer Sheath	5 French	.035"
Distal Tip	½" Radius Curve	½" Radius Curve
Length	200 cm	210 cm
Number of Lumens	1	2
Sterility	Sterile, disposable	Sterile, disposable

Testing: Biocompatibility has been established for the patient contacting materials through a history of use in other similar medical devices.

Functional testing conducted per approved protocol. Samples were subjected to visual, dimensional, and functional analysis. All samples were deemed acceptable, in that test specifications were met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 1997

Ms. Linda Hensley
Regulatory Affairs Specialist
Wilson-Cook Medical, Inc.
4900 Bethania Station Road
Winston-Salem, North Carolina 27105

Re: K972674
Wilson-Cook Needle Knife Papillotome
Dated: July 11, 1997
Received: July 16, 1997
Regulatory Class: II
21 CFR §876.4300/Product Code: 78 KNS

Dear Ms. Hensley:

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 (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 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/dsmamain.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

510(k) Number (if known): K972614

Device Name: Wilson-Cook Needle Knife Papillotome

Indications For Use: The Wilson-Cook Needle Knife Papillotome is used for accessing the common bile duct when standard cannulation methods have been exhausted. This device is supplied sterile and is intended for single use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert A. Ochs
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972614

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)