K033203

DEC 19 2003

ATTACHMENT D: 510(k) Summary of Safety and Effectiveness

SPONSOR:	Wilson-Cook Medical 4900 Bethania Station Road Winston-Salem, NC 27105
CONTACT/SUBMITTER:	Marge Walls-Walker Regulatory Affairs Specialist [336] -744-0157 Ex.290
DATE OF SUBMISSION:	September 30, 2003
DEVICE:	Tri-Tome Select Plus
Trade Name: Common Name: Classification:	Tri-Tome Select Plus Sphincterotome Unit, Electrosurgical, Endoscopic w/w/o Accessories, Class II 21 CFR § 876.4300
PREDICATE DEVICES:	Wilson-Cook Sphincterotome/Papillotome (k901443) Microvasive Autotome™ RX (k013153)
INTENDED USE:	Wilson-Cook's Tri-Tome Select Plus Sphincterotome is intended for cannulation of the ductal system and for sphincterotomy.
DEVICE DESCRIPTION:	The proposed Tri-Tome Select Plus Sphincterotome is a triple-lumen sphincterotome. It is capable of accommodating a .035" wire guide while allowing simultaneous injection of contrast media through separate lumens.
COMPARISON OF CHARACTERISITICS:	We believe the proposed device to be substantially equivalent to currently marketed triple-lumen transendoscopic sphincterotomes.
PERFORMANCE DATA:	We believe the proposed device to be substantially equivalent to the named predicates in terms of performance characteristics tested and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2003

Ms. Marge Walls-Walker
Regulatory Affairs Specialist
Wilson-Cook Medical
GI Endoscopy
4900 Bethania Station Road
WINSTON-SALEM NC 27105

Re: K033203
Trade/Device Name: Wilson-Cook Tri-Tome Select Plus Sphincterotome
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: 78 KNS
Dated: September 30, 2003
Received: October 2, 2003

Dear Ms. Walls-Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 033 203

Device Name: Wilson-Cook Tri-Tome Select Plus Sphincterotome

Indications for Use:

Used for cannulation of the ductal system and for sphincterotomy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only ✓ OR Over-the-Counter_____
(Per 21 CFR § 801.109

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033203