

K052051

AUG 5 - 2005

**ATTACHMENT F: 510(k) Summary**

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**SPONSOR:** Wilson-Cook Medical  
4900 Bethania Station Road  
Winston-Salem, NC 27105

**CONTACT/SUBMITTER:** Marge Walls-Walker  
Regulatory Affairs Manager  
[800] 245-4707 Ex.6290

**DATE OF SUBMISSION:** July 28, 2005

**DEVICE:** OMNI™ Sphincterotome

Trade Name: OMNI™ Sphincterotome  
Common Name: Sphincterotome  
Classification: Unit, Electrosurgical, Endoscopic w/w/o  
Accessories, Class II  
21 CFR § 876.4300

**PREDICATE DEVICES:** Wilson-Cook Triple Tome Select Plus  
Sphincterotome (k033203)

**INTENDED USE:** Wilson-Cook's OMNI™ Sphincterotome is  
intended for cannulation of the ductal system  
and sphincterotomy.

**DEVICE DESCRIPTION:** The proposed OMNI™ Sphincterotome is a  
triple-lumen sphincterotome. It is capable of  
accommodating wire guides from .018" to .035"  
in diameter while allowing simultaneous injection  
of contrast media through separate lumens.

**COMPARISON OF CHARACTERISTICS:** We believe the proposed device to be  
substantially equivalent to currently marketed  
triple-lumen transendoscopic sphincterotomes  
with respect to Intended Use and Method of  
Operation. The subject sphincterotome also  
incorporates DomeTip™ technology and a  
breakthrough catheter feature.

**PERFORMANCE DATA:** We believe the proposed device to be  
substantially equivalent to the named predicate  
in terms of performance characteristics tested  
and biocompatibility.



AUG 5 - 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K052051

Trade/Device Name: Wilson-Cook OMNI™ Sphincterotome  
Regulation Number: 21 CFR §876.4300  
Regulation Name: Endoscopic electrosurgical unit and accessories  
Regulatory Class: II  
Product Code: KNS  
Dated: July 28, 2005  
Received: July 29, 2005

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html>.

Sincerely yours,



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

Enclosure

K05 2051

510(k) Number (if known): K

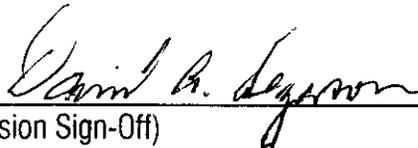
Device Name: Wilson-Cook OMNI™ Sphincterotome

Indications for Use:

Used for cannulation of the ductal system and sphincterotomy.

**(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, and  
Radiological Devices

510(k) Number K05 2051

Prescription Use Only   
(Per 21 CFR § 801.109)

OR

Over-the-Counter