



# U.S. Department of Health & Human Services

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## Food and Drug Administration

### SAVE REQUEST

**USER:** (cwf)  
**FOLDER:** K052051 - 83 pages  
**COMPANY:** WILSON-COOK MEDICAL, INC. (WILSCOOKMEDI)  
**PRODUCT:** UNIT, ELECTROSURGICAL, ENDOSCOPIC (WITH OR WITHOUT ACCESSORIES) (KNS)  
**SUMMARY:** Product: OMNI SPHINCTEROTOME

**DATE REQUESTED:** Aug 24, 2016

**DATE PRINTED:** Aug 24, 2016

**Note:** Printed



K052051

AUG 5 - 2005

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

---

**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.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 5 - 2005

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)

*David A. Segerson*

(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



AUG 5 - 2005

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 electro-surgical 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.

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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.

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

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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)

*David A. Seymour*

(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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
 Center for Devices and  
 Radiological Health  
 Office of Device Evaluation  
 Document Mail Center (HFZ-401)  
 9200 Corporate Blvd.  
 Rockville, Maryland 20850

July 29, 2005

WILSON-COOK MEDICAL, INC.  
 4900 BETHANIA STATION RD. &  
 5951 GRASSY CREEK BLVD.  
 WINSTON-SALEM, NC 27105  
 ATTN: MARGE WALLS-WALKER

510(k) Number: K052051  
 Received: 29-JUL-2005  
 Product: OMNI SPHINCTEROTOME

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman  
 Supervisory Consumer Safety Officer  
 Office of Device Evaluation  
 Center for Devices and Radiological Health

K092051



**Wilson-Cook Medical  
GI Endoscopy**  
4900 Bethania Station Road  
Winston-Salem, NC 27105  
Phone: 336 744-0157  
Customer Service: 800 245-4717  
Fax: 336 744-1147 • 800 743-1147  
www.cookgroup.com

FOIA/CDRH/DOJ  
7/28/2005

July 28, 2005

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, MD 20850

**RE: Premarket Notification for Wilson Cook OMNI™ Sphincterotome**

Dear Sir or Madam,

The purpose of this letter is to notify the Food and Drug Administration, pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act, that Wilson-Cook Medical Inc. intends to manufacture and market the Wilson-Cook OMNI™ Sphincterotome. The Wilson-Cook OMNI™ Sphincterotome is used for cannulation of the ductal system and to perform sphincterotomy.

The following information is submitted pertaining to the Wilson-Cook OMNI™ Sphincterotome:

1. **Classification Name/Code:** Unit, Electrosurgical, Endoscopic with or without Accessories, 78 KNS.
2. **Classification:** FDA has classified similar devices as Class II, 21 CFR§ 876.4300. This device falls within the purview of the Gastroenterology and Urology Device Panel within the Division of Reproductive, Abdominal and Radiological Devices.
3. **Trade Name/Proprietary Name:** Wilson-Cook OMNI™ Sphincterotome
4. **Common/Usual Name:** Sphincterotome
5. **Establishment Registration Number:** 1037905
6. **Performance Standards:** No performance standards have been established under Section 514 of the Federal Food, Drug and Cosmetic Act applicable to Electrosurgical Endoscopic Units or their accessories.
7. Sample package labels for the Wilson-Cook OMNI™ Sphincterotome are included in **Attachment A**.
8. A copy of the draft Instructions for Use for the Wilson-Cook OMNI™ Sphincterotome are included in **Attachment B**.
9. This device is similar with respect to Intended Use and Technological characteristics to the following predicate devices:

SK11  
52  
50 19  
H

- *Wilson-Cook Tri Tome Select Plus Sphincterotome*, k033203, SE Decision Date 12/19/03, manufactured by Wilson-Cook Medical.

Complete device comparisons can be found in **Table 1**.

10. The Wilson-Cook OMNI™ Sphincterotome Intended Use Statement is included in **Attachment G**.
11. Refer to **Section 1.0-8.0** for a complete description of the Wilson-Cook OMNI™ Sphincterotome.
12. The 510(k) Summary is included in **Attachment F**.
13. The Truthful and Accurate Statement can be found in **Section 10.0**.
14. The Declaration of Conformity to Design Controls can be found in **Section 9**.

Wilson-Cook considers its intent to market this product as confidential, commercial information and we request that it be considered as such by FDA. Information contained herein should not be made available through the Freedom of Information Act, except as required by law.

Should there be any questions pertaining to this submission, please do not hesitate to contact me at [800] 245-4707 ext. 6290.

Sincerely,



Marge Walls-Walker  
Regulatory Affairs Manager  
Wilson-Cook Medical

20

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.	
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:			
1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louise, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: <a href="http://www.fda.gov/cdrh/mdufma/faqs.html#3a">http://www.fda.gov/cdrh/mdufma/faqs.html#3a</a> . You are responsible for paying all fees associated with wire transfer. 6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.			
--> 1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  WILSON COOK MEDICAL INC 4900 Bethania Station Road Winston-Salem NC 27105 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)		2. CONTACT NAME Marge Walls-Walker 2.1 E-MAIL ADDRESS mwalls-walker@wilsoncook.com 2.2 TELEPHONE NUMBER (include Area code) 336-7440157 6290 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 336-7440157 6290	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <a href="http://www.fda.gov/dc/mdufma">http://www.fda.gov/dc/mdufma</a> )			
Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)		3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: null			
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.			
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)			
<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005) (b)(4)			14-Mar-2005

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Special 510(k): Wilson-Cook OMNI Sphincterotome

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**Attachments**

Attachment A	OMNI™ Sphincterotome Labels
Attachment B	OMNI™ Sphincterotome Instructions for Use
Attachment C	Biocompatibility for Breakaway Tubing
Attachment D	OMNI™ Advertising Brochure
Attachment E	DomeTip™ Advertising Brochure
Attachment F	510k Summary
Attachment G	Intended Use Statement
Attachment H	OMNI™ Sphincterotome, OMNI™ Preloaded Sphincterotome Engineering and OMNI™ Sphincterotome Packaging Drawings

**1.0 Intended Use**

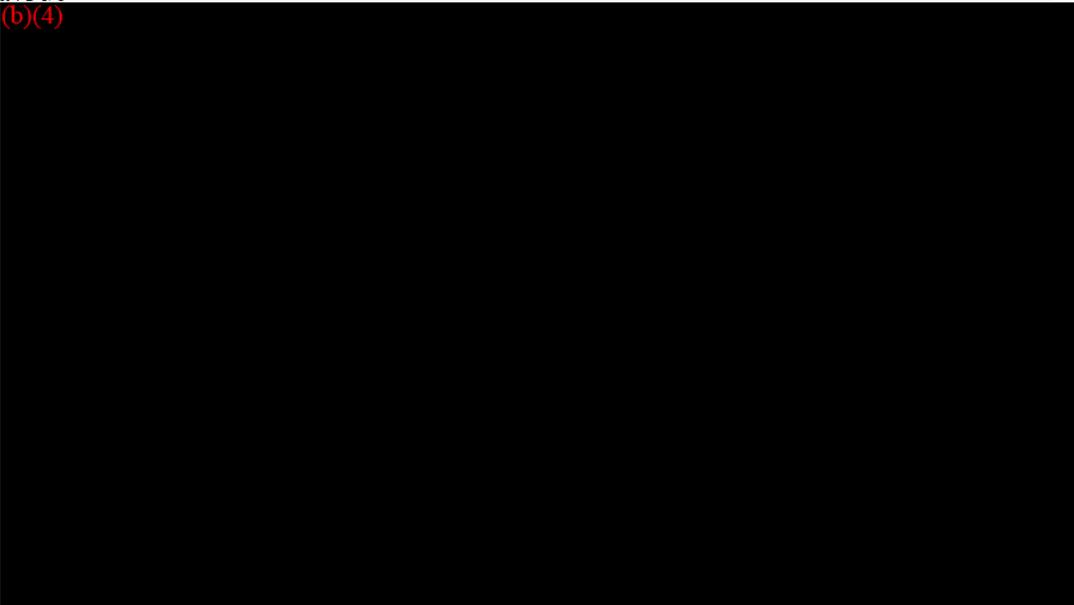
The Wilson-Cook OMNI™ Sphincterotome is intended for cannulation of the ductal system and sphincterotomy. This device is supplied sterile and intended for single use only.

**2.0 Description of the Modified Wilson-Cook OMNI™ Sphincterotome (Subject of Special 510(k))**

The modified Wilson-Cook OMNI™ Sphincterotome consists of a (b)(4) catheter attached to a handle at the proximal end and incorporating a stainless steel cutting wire in the distal portion. The handle provides an active cord connection as well as a feature for controlling the cutting wire. The catheter has (b) distinct lumens; one each for wire guide access, the cutting wire and contrast injection. The catheter has separate Luer hubs for wire guide access and contrast injection. The distal end of the catheter is marked locations to guide the physician in correct cutting wire orientation.

(b)(4)



- (b)(4)
  - 
  -
- 

For any of the three methods above, once the sphincterotomy is completed, removal of the OMNI™ Sphincterotome catheter is identical. Verifying that the wire guide is locked in place, the user pulls back on the catheter, allowing the catheter and wire guide to separate

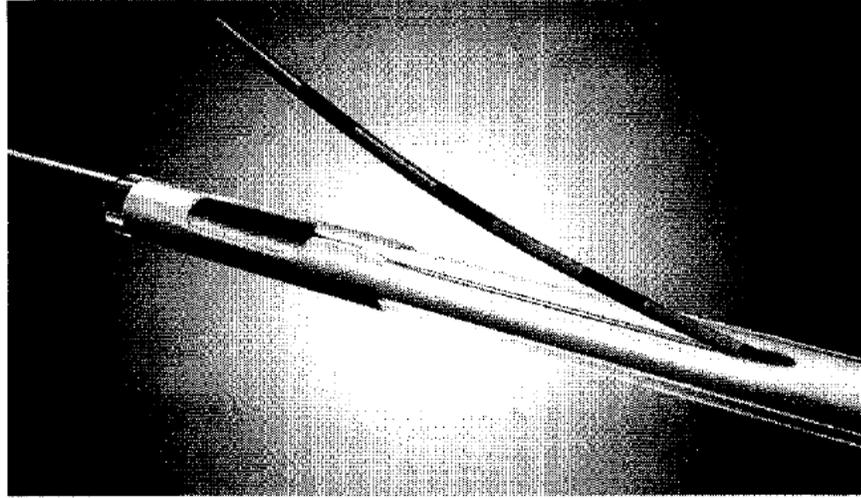
via the breakthrough section of the wire guide lumen. The catheter is pulled back until the metal band (b) from the distal end of the catheter passes back through the cap and wire lock and resistance is felt. This indicates the end of the breakthrough section of the catheter. At this point, the wire guide is unlocked and the catheter removed over the remaining proximal portion of the wire guide. Use of the Fusion Short Wire (k 033754) is recommended for these procedures; however, traditional long wires may be used. If a long wire guide is used it may be introduced through either the WCP or the Proximal Wire port (PWP). Once the sphincterotomy is completed, the wire may be locked in place and the catheter separated as above if the long wire was introduced through the WCP. If the long wire is introduced through the PWP, traditional exchange techniques are used.

Please see **Figure 1** below for an illustration of the complete device. Please see **Figure 2** below for an image of the breakthrough channel feature. Please see **Attachment D** for advertising material that illustrates the peel away feature. Please see **Attachment H** for the Engineering Drawing.

(b)(4)

### Figure 1: Illustration of the Wilson-Cook OMNI™ Sphincterotome

An additional feature that has been introduced with the OMNI™ Sphincterotome is a dome shaped cannulating tip. This modification has the potential to be less traumatic to the papillary fronds than traditional tips as the Sphincterotome is navigated toward the sphincter. Please see **Attachment E** for the DomeTip™ advertisement that illustrates this feature.



**Figure 2: Breakthrough Channel Image**

### **3.0 Comparison to the Predicate Wilson-Cook Tri Tome Select Plus Sphincterotome (k033203).**

The modified Wilson-Cook OMNI™ Sphincterotome is substantially equivalent to the referenced device with respect to primary operating mechanisms and Intended Use. Both sphincterotomes are triple-lumen to allow for injection of contrast media, passage of wire guide and cutting wire attachment. Both devices share identical materials of construction with the exception of the breakthrough catheter wall, are supplied sterile and intended for single use only. The primary modifications to the OMNI™ are the reshaping of the distal tip into a dome configuration, the breakthrough catheter wall and the relocation of the WCP from (b)(4) to allow for easier access to the wire by nursing

(b)(4)

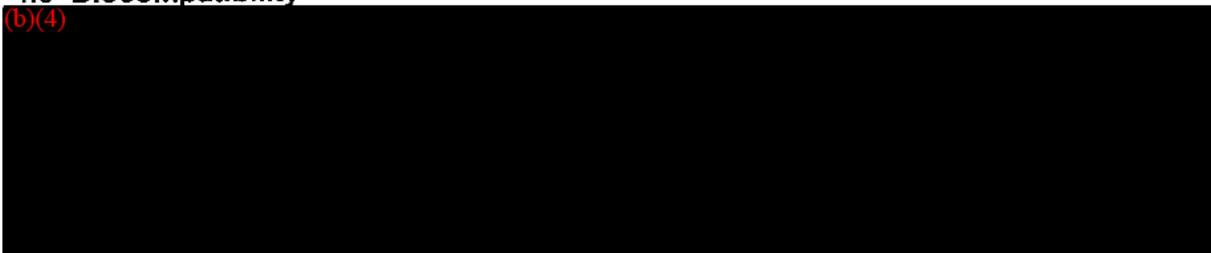
The modifications to the Wilson Cook Tri Tome Select Plus Sphincterotome have been assessed through our Design Control Process. This process includes a Risk Assessment as well as Design Verification/Validation to demonstrate that the modified device meets predetermined Acceptance Criteria. Please refer to **Section 8** for the Risk Analysis Summary that addresses specific risks to the patient potentially introduced by the modifications made and the methods used to minimize or eliminate the risks, the acceptance criteria, results and the conclusions.

**Table 1: PREDICATE DEVICE COMPARISON**

<b>Parameter</b>	<b>Tri Tome Select Plus Sphincterotome (k033203)</b>	<b>OMNI™ Sphincterotome (subject of this 510(k))</b>
<b>Intended Use</b>	Used for cannulation of the ductal system and sphincterotomy	Used for cannulation of the ductal system and sphincterotomy
<b>Supplied Sterile</b>	Yes, EO	Yes, EO
<b>Duration of Use</b>	Disposable	Disposable
<b>Dimension<sub>1</sub></b>	25 mm, monofilament cutting/ bowing wire	25 mm, monofilament cutting/ bowing wire
<b>Dimension<sub>2</sub></b>	Triple Lumen	Triple Lumen
<b>Dimension<sub>3</sub></b>	Platinum band ~6cm from distal tip (marks IDE port)	Platinum band ~6cm from distal tip (marks terminal end of breakthrough catheter)
<b>Wire Guide</b>	.035, .025 compatible; adaptable to both short and long wire techniques	.018", .021", .025", .035" compatible; adaptable to both short and long wire techniques
<b>Wire Control Port (s)</b>	Yes; at 160 cm distal and 6 cm proximal from patient contact tip.	Yes; at 172 cm from patient contact tip.
<b>Material<sub>1</sub></b>	PTFE catheter w/ Trans-Tech B ink markings	PTFE catheter w/ breakthrough wall in wire guide lumen and Trans-Tech B ink markings
<b>Material<sub>2</sub></b>	Stainless Steel Cutting Wire	Stainless Steel Cutting Wire
<b>Endoscope Compatibility</b>	4.2 mm	3.2 mm

**4.0 Biocompatibility**

(b)(4)



**Table 2: BIOCOMPATIBILITY SUMMARY**

TEST	PTFE catheter w/Breakthrough wall
(b)(4)	

Non-patient contact materials include Lexan handle components, versafit shrink tubes, cannulated metal hubs and a platinum anchor on the interior of the catheter.

**5.0 PACKAGING INFORMATION**

The Wilson-Cook OMNI™ Sphincterotome will be loaded into a racetrack holder, heat sealed Tyvek and Mylar pouch and supplied sterile. The OMNI™ will also be supplied pre-loaded with a .035" wire guide, specifically the Fusion Short Wire as cleared by k033754.

**For an example of the Package Labels, please see Attachment A.**

**For an example of the Draft Instructions for Use, please see Attachment B.**

Section III in the IFU's, refers specifically to the breakthrough catheter feature of the OMNI™ Sphincterotome.

**6.0 Sterilization Information**

The Wilson-Cook OMNI™ Sphincterotome is supplied sterile in a Tyvek and Mylar pouch. This device once packaged is sterilized using a validated ethylene oxide gas cycle obtaining a SAL of 10<sup>-6</sup>. Validation follows the recommendations of AAMI Standard 11135: "Medical Devices-Validation and Routine Control of Ethylene Oxide Sterilization" as well as EN 550: "Sterilization of medical devices-Validation and routine control of Ethylene Oxide sterilization".

The ethylene oxide (EO) residual levels will be verified to be less than the maximum levels established for this device. **The maximum levels (per Federal Register Notice 27482, June 1978) are for devices contacting mucosa and can be found in Table 3 below:**

**Table 3: ETHYLENE OXIDE RESIDUALS**

(b)(4)	
--------	--

### 7.0 Design Control Summary

The Wilson-Cook modified OMNI™ Sphincterotome was developed under Wilson-Cook internal Design Control procedures as required by 21 CFR § 820.30.

Wilson-Cook's Design Control Procedures are inclusive of the following elements:

- Design Planning/Design Input
- Risk Analysis
- Design Output/Design Verification
- Design Review/Design Transfer
- Design Validation
- Design Changes
- Process Validation

A Risk Analysis/Design Verification Summary for the Wilson-Cook OMNI™ Sphincterotome can be found in **Section 8**.

A Declaration of Conformance with Design Controls can be found in **Section 9**.

### 8.0 Risk Analysis/ Design Verification Testing

For the Wilson-Cook OMNI™ Sphincterotome, the risks identified were relative to the performance requirements, as specified by our internal procedure for Risk Analysis. Please see **Table 4** for a summary of those risks to the patient potentially introduced by the modifications made and the methods used to minimize or eliminate the risks, the acceptance criteria, results and the conclusions.

**Table 4: RISK ANALYSIS SUMMARY**

Risk	Design Activity to Reduce or Eliminate	Acceptance Criteria	Results
(b)(4)			

**Risk Analysis Summary (con't)**

Risk	Design Activity to Reduce or Eliminate	Acceptance Criteria	Results
(b)(4)			

**Conclusion:**

All results obtained during our Design Verification and Validation for this product line and summarized above have been deemed acceptable. Therefore we consider this modification to the Wilson Cook Tri Tome Select Plus Sphincterotome to be acceptable with respect to Design Verification and Validation activities.

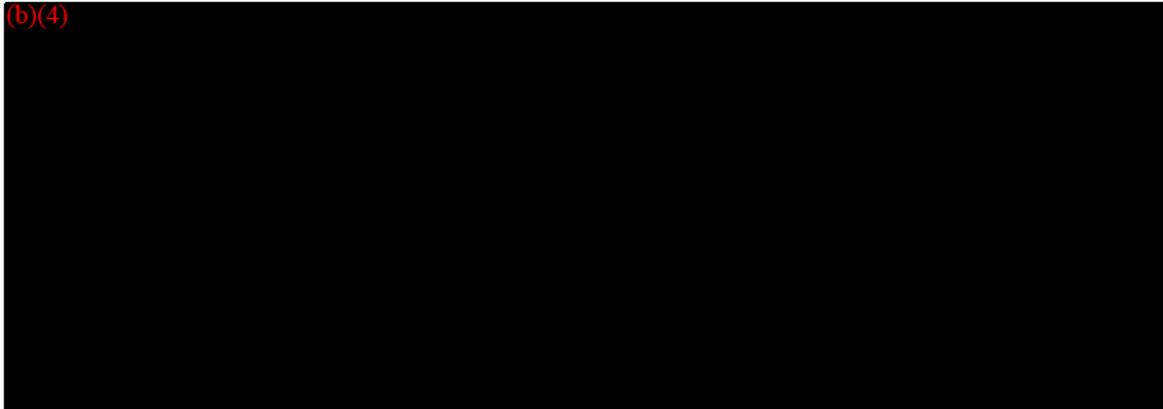
Results of testing provide reasonable assurance that the Wilson Cook OMNI™ Sphincterotome, subject of this 510(k), will function as intended and maintain integrity throughout use.

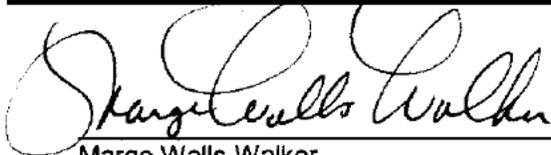
**9.0 Declaration of Conformance with Design Controls**

Wilson-Cook Medical, Inc. hereby declares that Design Control and Risk Analysis for this product were conducted in accordance with our internal procedures. We further declare that all verification activities associated with the Risk Analysis were performed and approved by the individual(s) as designated by our internal procedures. The results of our verification activities for this project demonstrated our compliance to the predetermined Acceptance Criteria.

Wilson-Cook Medical, Inc. further declares conformity as applicable to all commonly recognized Quality System Requirements (QSR, ISO 9001, MDD) including compliance to applicable Design Control requirements specified per 21 CFR § 820.30. Records of Design Control activities in the form of our Design History File are maintained and as required can be made available for review to US or International Regulatory bodies.

(b)(4)



  
\_\_\_\_\_  
Marge Walls-Walker  
Regulatory Affairs Manager

7.28.05  
Date

## 10.0 Truthful and Accurate Statement

### TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR§ 807.87 (j)]

I certify that in my capacity as a Regulatory Affairs Manager at Wilson-Cook Medical Inc., I believe to the best of my knowledge that all data and information submitted in the Pre-market Notification are truthful and accurate and that no material fact has been omitted.



Marge Walls-Walker  
Regulatory Affairs Manager  
July 28, 2005

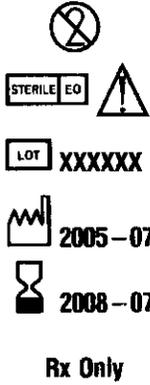
Patient Charge      Inventory      Patient Chart

Reorder No.: FS-OMNI	Reorder No.: FS-OMNI	Reorder No.: FS-OMNI
Description: FUSION TRIPLE LUMEN SPHINCTEROTOME	Description: FUSION TRIPLE LUMEN SPHINCTEROTOME	Description: FUSION TRIPLE LUMEN SPHINCTEROTOME
Lot No.: XXXXXX	Lot No.: XXXXXX	Lot No.: XXXXXX

Reorder No.: FS-OMNI-185	Reorder No.: FS-OMNI-185	Reorder No.: FS-OMNI-185
Description: FUSION TRIPLE LUMEN SPHINCTEROTOME	Description: FUSION TRIPLE LUMEN SPHINCTEROTOME	Description: FUSION TRIPLE LUMEN SPHINCTEROTOME
Lot No.: XXXXXX	Lot No.: XXXXXX	Lot No.: XXXXXX

**REF FS-OMNI**

**FUSION TRIPLE LUMEN SPHINCTEROTOME**  
**MONOFILAMENT CUTTING WIRE: 25 MM.**  
**TIP: DOMETIP**  
**SHEATH: 7 FR./200 CM.**  
**COMPATIBLE WIRE GUIDE: .035"**  
**WIRE GUIDE SOLD SEPARATELY**  
**MINIMUM ACCESSORY CHANNEL: 3.2 MM.**  
**FORMULATOR STYLET WIRE**  
**DISPOSABLE - SINGLE USE ONLY**



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 GI Endoscopy   
 4900 Bethania Station Road • Winston-Salem, NC 27105

17411/0300

**REF FS-OMNI-185**

**FUSION TRIPLE LUMEN SPHINCTEROTOME**  
**PRE-LOADED W/.035"/185 CM. FUSION WIRE**  
**MONOFILAMENT CUTTING WIRE: 25 MM.**  
**TIP: DOMETIP**  
**SHEATH: 7FR./200 CM.**  
**COMPATIBLE WIRE GUIDE: .035"**  
**MINIMUM ACCESSORY CHANNEL: 3.2 MM.**  
**FORMULATOR STYLET WIRE**  
**DISPOSABLE - SINGLE USE ONLY**



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17411/0300

## **C O N F I D E N T I A L**

**D R A F T** – 02/10/05 – 3:00 p.m.

### **Fusion™ Sphincterotome and OMNI™ Sphincterotome**

#### **IMPORTANT INFORMATION**

Please review prior to use.

#### **INTENDED USE**

The device is used for cannulation of the ductal system and sphincterotomy. This device is supplied sterile and intended for single use only.

#### **NOTES**

If the package is opened or damaged when received, do not use. Visually inspect with particular attention to kinks, bends and breaks. If an abnormality is detected that would prohibit proper working condition, do not use. Please notify Wilson-Cook for return authorization.

#### **CONTRAINDICATIONS**

Contraindications include those specific to ERCP and any procedures to be performed in conjunction with sphincterotomy. Contraindications to sphincterotomy include but are not limited to: coagulopathy and inability to properly position the sphincterotome cutting wire.

#### **POTENTIAL COMPLICATIONS**

Potential complications associated with ERCP include, but are not limited to: pancreatitis, cholangitis, aspiration, perforation, hemorrhage, infection, sepsis, allergic reaction to contrast or medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.

#### **PRECAUTIONS**

Refer to package label for minimum channel size required for this device.

This device meets the recognized standard for high frequency electrosurgical leakage current (ANSI/AAMI HF 18). The maximum rated input voltage for this device is 1.67 kVp-p.

Any electrosurgical accessory constitutes a potential electrical hazard to the patient and the operator. Possible adverse effects include, but are not limited to: fulguration, burns, nerve and/or muscle stimulation and cardiac arrhythmia.

Before using this device, follow the recommendations provided by the electrosurgical unit manufacturer to ensure patient safety through the proper placement and utilization of the patient return electrode. Ensure a proper path from the patient return electrode to the electrosurgical unit is maintained throughout the procedure.

Switch the electrosurgical unit to the “off” position when it is not in use.

When applying current, ensure the cutting wire is completely out of the endoscope. Contact of the cutting wire with the endoscope may cause grounding, which can result in patient injury, operator injury, a broken cutting wire, and/or damage to the endoscope.

If a non-protected wire guide is used in the sphincterotome, it must be removed prior to applying electrosurgical current.

Do not over flex or bow the tip beyond 90°, as this may damage or cause the cutting wire to break.

The elevator should remain open/down when advancing or retracting the sphincterotome.

## **SYSTEM PREPARATION**

1. Upon removing the device from the package, uncoil and straighten the sphincterotome. Carefully **remove the precurved stylet from the cannulating tip. Note:** Do not apply manual pressure to the tip or cutting wire of the sphincterotome to influence orientation, as this may result in damage to the device. **Note:** Do not exercise the handle while the device is coiled or the precurved stylet is in place, as this may cause damage to the sphincterotome and render it inoperable.

2. With the electrosurgical unit off, prepare the equipment. The active cord fittings should fit snugly into both the device handle and the electrosurgical unit.
3. Attach the Wire Guide Locking Device to the endoscope accessory port (if applicable).

## **INSTRUCTIONS FOR USE**

### **I. If using the Intra Ductal Exchange (IDE) port and the Ultra Short Wire (USW). (See Fig. 1)**

**Note:** Remove the Wire Stop from its retaining clip.

1. Ensure that the Wire Stop is disengaged from the Proximal Wire Port (PWP) hub and ensure that the distal tip of the Wire Stop is proximal to the IDE port.
2. Insert the distal tip of the wire guide into the IDE port and advance until it is flush with the distal tip of the sphincterotome.
3. Advance the Wire Stop handle until it reaches the PWP hub and connect the Luer lock securely to the PWP hub.
4. Advance the tip of the sphincterotome through the cap of the Wire Guide Locking Device and continue advancing until it is endoscopically visible.
5. Disengage the Wire Stop by releasing the handle from the PWP hub and remove Wire Stop from catheter.
6. Cannulate the common bile duct and verify the correct placement of the cutting wire in the papilla, adjust as necessary.
7. Following cannulation, contrast may be injected through the injection port to fluoroscopically confirm position of the device.

8. Following the electrosurgical unit manufacturer's instructions, verify the desired settings and proceed with sphincterotomy.

9. Upon completion of sphincterotomy, turn the electrosurgical unit off.

10. Disconnect the active cord from the device handle and from the electrosurgical unit. Wipe the active cord with a damp cloth to remove all foreign matter. Store in a loose coil.

**Note:** Wrapping the active cord tightly may damage the device.

**Note:** The previously placed wire guide may be left in position, in order to facilitate introduction of other wire-guided devices. If the wire guide is to remain in place while the device is withdrawn, utilize the following steps:

11. Prior to removing the device, utilize the reference marks on the catheter to ensure that the IDE port is within the ductal system.

12. Align the distal tip of the wire with the distal tip of the catheter by retracting the wire guide until the IDE Wire Mark is aligned with the distal end of the IDE Catheter Mark. *(See Fig. 2)*

13. Retract the wire guide until the color indicator passes the proximal end of the IDE Catheter Mark, disengaging the wire guide from the wire guide lumen. *(See Fig. 3)*

**Note:** Fluoroscopically visualize the radiopaque band at the IDE port. When the radiopaque distal tip of the wire guide passes the band, a disengagement from the wire guide lumen will occur.

14. Advance the disengaged wire guide to maintain ductal access.

15. Lock the wire guide into the Wire Guide Locking Device and remove the sphincterotome from the endoscope accessory channel.

16. Upon completion of the procedure, dispose of the device per institutional guidelines for biohazardous medical waste.

**II. If using the Proximal Wire Port (PWP) and a pre-positioned long wire guide. (See Fig. 1)**

**Note:** For best results, the wire guide should be kept wet.

1. Remove Wire Stop (if applicable).
2. Advance sphincterotome over the pre-positioned wire guide ensuring that the wire exits the catheter at the PWP.
3. Continue advancing the device until it is endoscopically visible.

**REFER TO STEPS 6-10 IN “SECTION I”, THEN RESUME WITH STEP 4 BELOW:**

4. Remove the device using standard long wire exchange technique.
5. Upon completion of the procedure, dispose of the device per institutional guidelines for biohazardous medical waste.

**III. If using the Wire Control Port (WCP) and an Ultra Short Wire or long wire guide. (See Fig. 4)**

1. Advance the tip of the sphincterotome through the cap of the Wire Guide Locking Device and continue advancing until it is endoscopically visible.
  2. Introduce a wire guide into the WCP and advance into the duct of choice, separating the wire guide from the catheter. (See Figs. 5 & 6)

**REFER TO STEPS 6-10 IN “SECTION I”, THEN RESUME WITH STEP 3 BELOW:**

3. To withdraw the sphincterotome from the endoscope, ensure the wire guide is locked in place, and then pull back on the catheter, allowing the wire guide lumen to separate from the wire guide until the metal band is visible at the Wire Guide Locking Device and resistance is felt. (*See Fig. 7*)
4. Unlock the wire guide from the Wire Guide Locking Device, completely remove the sphincterotome from the wire guide, and re-lock the wire guide.
5. Upon completion of the procedure, dispose of the device per institutional guidelines for biohazardous medical waste.

Fusion is a trademark of Wilson-Cook Medical Inc.

Cook is a registered trademark of Cook Incorporated.

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*[INSERT SYMBOLS: "RX Only" / Sterile-EO / "One-time use only"]*

*[C E symbol] 0123*

**Wilson-Cook Medical Inc.**  
4900 Bethania Station Road  
Winston-Salem, North Carolina 27105  
USA

**Cook Ireland**  
O'Halloran Road  
National Technology Park  
Limerick  
Ireland

Confidential

Lab No.

04T\_61228\_11

V0014\_130

P.O. No.

57189

**STUDY TITLE:**

CYTOTOXICITY STUDY USING THE ISO ELUTION METHOD

(1X MEM Extract)

**TEST ARTICLE:**

Grey Peel-away Teflon tubing with red, green, silver, copper and gold Trans-Tech inks

**IDENTIFICATION NO.**

Lot: PD112304-03

(b)(4)

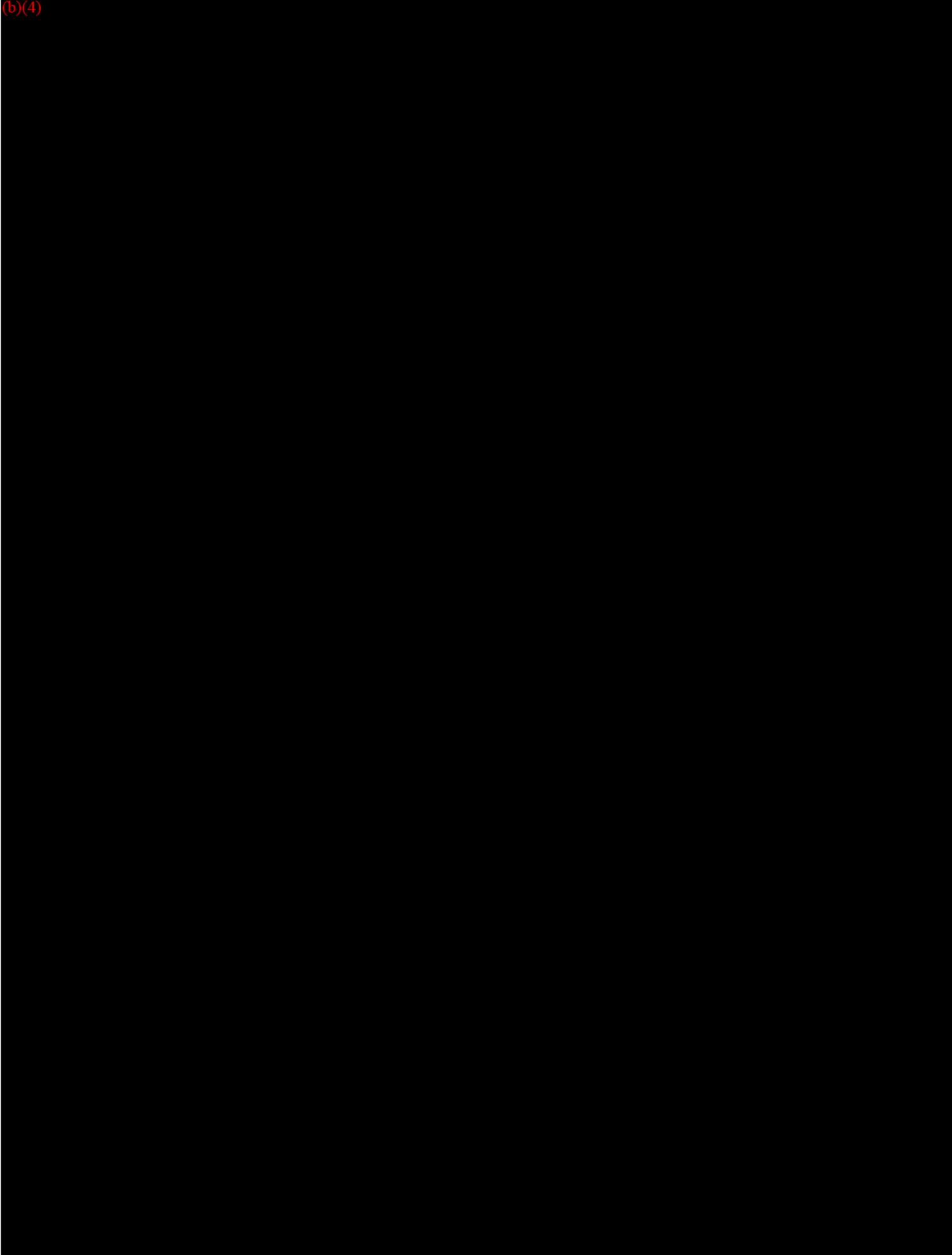


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SUMMARY

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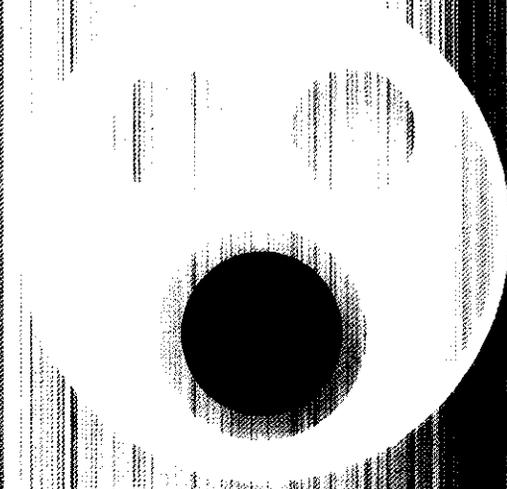








**COOK**<sup>®</sup>  
Wilson-Cook Medical  
GI Endoscopy



**COOK**  
The new 11mm channel design

**FUSION**<sup>™</sup>

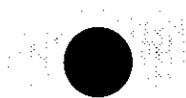
## Introducing Fusion OMNI™ The new face of channel design

**A Breakthrough in Catheter Design!** Thanks to the ingenuity of Wilson-Cook engineers, catheter design has “evolved” in two major ways.

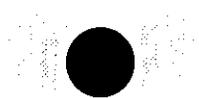
The revolutionary **OMNI Breakthrough Channel™** features innovative technology that allows the assistant, if desired, to control the wire guide, and gives you the option to initiate an ERCP with or without a wire guide. The OMNI-Tome is compatible with a 3.2 mm channel.

All OMNI devices feature the distinctively contoured patent pending **DomeTip™**, which completely eliminates the “flat” distal tip of conventional cannulating devices, allowing smoother navigation through the papillary fronds.

- The OMNI is compatible with any length or diameter wire guide
- The solid catheter maintains structural strength for maximum pushability
- Allows flushing the wire guide lumen of the device



**U-Channel**



**C-Channel**



**Solid Channel**

(Breakthrough Channel Design)

### Available **Fusion OMNI** products

Sphincterotomes	French Size	Cutting Wire Length	Tip
† <b>FS-OMNI</b>	7 FR	25 mm	DomeTip
*† <b>FS-OMNI-185</b>	7 FR	25 mm	DomeTip

Catheters	French Size	Length	Tip
<b>FS-GT-OMNI</b>	7 FR	200 cm	DomeTip

\* Preloaded with Fusion 185 cm Ultra Short Wire.

† Pending 510 (k). Not available for sale in the United States.

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## OMNI with Breakthrough Channel Design

### How does it work?

#### STEP 1

Insert the wire guide into the Wire Control Port of the OMNI device. With assistant wire control option designed into the device, the physician or assistant can manipulate the wire guide until access to the desired duct is obtained. Once access is achieved, "POP" (Press-Out-Point) the wire guide through the patent pending Breakthrough Channel.



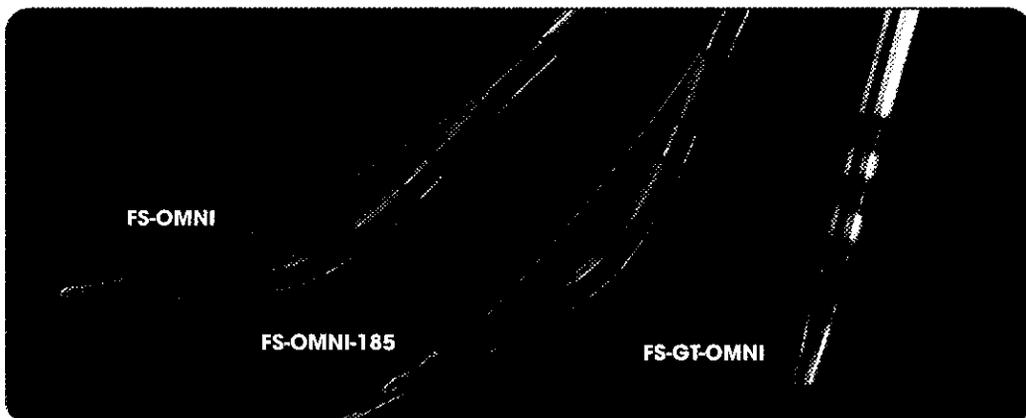
#### STEP 2

Once the "POP" of the wire guide is achieved, continue separating the wire guide from the catheter to advance more wire as needed.



#### STEP 3

The wire guide can be separated down to the Wire Guide Locking Device where the physician can then control the wire guide. The wire guide can be locked and a "Zip" exchange performed using the OMNI Breakthrough Channel design.



***FUSION***<sup>™</sup>

**COOK**<sup>™</sup> Wilson-Cook Medical  
GI Endoscopy

800.457.4500 (US Only) or 336.744.0157  
[www.wilsoncook.com](http://www.wilsoncook.com)

E-19001/0405

COOK<sup>SM</sup>

Wilson-Cook Medical  
GI Endoscopy



The new shape of **access**

**DOMETIP**<sup>SM</sup>

---

## Introducing DomeTip™

### The new shape of access

Finally, an evolution in catheter tip design!

It's a long-standing clinical problem: Traditional flat-tip catheters are susceptible to becoming lodged in the papilla and/or the fronds within the duodenal end of the biliary ductal system. That's why we made the natural, organic progression from flat-tipped catheters the patent pending DomeTip devices.

By completely eliminating the "flat" tip at the distal end of conventional cannulating devices, the distinctively contoured DomeTip glides more smoothly through the papillary fronds.

As a result, the DomeTip devices are changing the shape of access with:

Easier access

Potentially less trauma

Ease-of-use that could save time

## Products that feature DomeTip design

### DASH Products

\*DASH-21-480

\*DASH-21

DASH-480

DASH-260

DASH-1

\*DASH-35-480

### Fusion Products

FS-25M-35

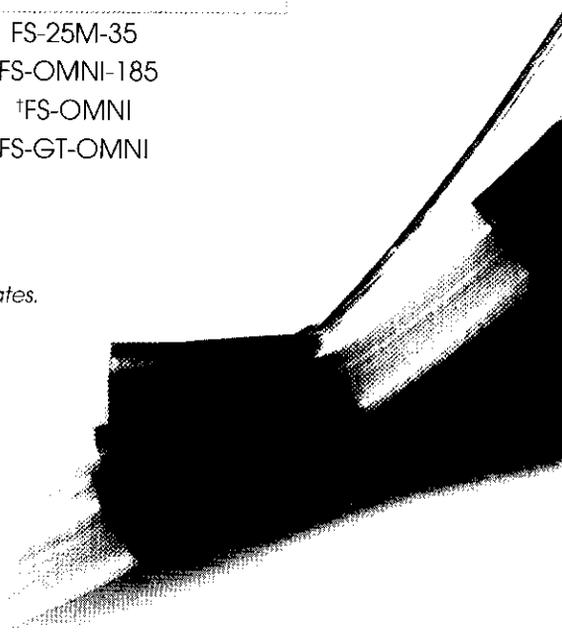
†FS-OMNI-185

†FS-OMNI

FS-GT-OMNI

\*Check for availability of DomeTip version.

†Pending 510 (k). Not available for sale in the United States.



DomeTip

**DOMETIP™**



**Fusion OMNI Sphincterotome**

Designed for potentially easier access through the papillary fronds.



70

**DOMETIP**

**COOK** Wilson-Cook Medical  
GI Endoscopy

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[www.wilsoncook.com](http://www.wilsoncook.com)

L-19002/0405

## ATTACHMENT F: 510(k) Summary

---

**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.

*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)

Prescription Use Only \_\_\_\_\_  
(Per 21 CFR § 801.109)

OR

Over-the-Counter \_\_\_\_\_











DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Memorandum

From: Reviewer(s) - Name(s) Mary Ed Zorn Rudman  
Subject: 510(k) Number K052051

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES  NO

- Truthful and Accurate Statement  Requested  Enclosed
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source  YES  NO Material of Biological Origin  YES  NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):  
 No Confidentiality  Confidentiality for 90 days  Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

II 876.4300, KNS, 78

Review: [Signature] ULDB (Date) AUG 5/05  
(Branch Chief) (Branch Code)

Final Review: [Signature] (Date) 8/5  
(Division Director)

SPECIAL 510(k): Device Modification  
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE RE: DOCUMENT NUMBER K052051

---

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)

K033202 Wilson-Cook Tri Tome Select Plus Sphinctertome

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).  
Cannulation of the ductal system and sphincterotomy.
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.  
**This change was for**
  - The reshaping of the distal tip into a dome configuration,
  - The breakthrough catheter wall as well as the relocation of the wire control port (WCP) from 166 cm to 172 cm.
  - Pre-loading of the guidewire into the sphincterotome.
  - Packaging changed to a racetrack holder.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics have been included and are accurate (Section 3, Table 1 on page 4).
5. A **Design Control Activities Summary** (Section 8 page 6, 7 and 8) which includes:
  - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
  - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
  - c) A declaration of conformity with design controls. The declaration of conformity should include:
    - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and

- ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

The sponsor provided partial risk analysis validation/verification activities. A template for the risk analysis activities was sent to them on August 2, 2005. The sponsor responded immediately with the revised risk analysis validation/verification activities, and upon review was found to be adequate.

**6. A Truthful and Accurate Statement (Section 10, Page 9) , a 510(k) Summary or Statement (Attachment F) and the Indications for Use Enclosure (Attachment G) were provided (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

*Mary P. Brennan*  
(Reviewer's Signature)

8/4/05  
(Date)

Comments

---

revised:8/1/03

REVISED:3/14/95

**THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).**

**"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION**

K052051

Reviewer: Mary Beth O'Brien, RN, MSN

Division/Branch: DRARD/ULDB

Device Name: Wilson-Cook OMNI™ Sphincterotome

Product To Which Compared (510(K) Number If Known):\_K033202 Wilson-Cook Tri Tome Select Plus Sphincterotome

		YES	NO	
1.	Is Product A Device	X		If NO = Stop
2.	Is Device Subject To 510(k)?	X		If NO = Stop
3.	Same Indication Statement?	X		If YES = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If YES = Stop NE
5.	Same Technological Characteristics?	X		If YES = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7.	Descriptive Characteristics Precise Enough?	X		If NO = Go To 10 If YES = Stop SE
8.	New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9.	Accepted Scientific Methods Exist?			If NO = Stop NE
10.	Performance Data Available?			If NO = Request Data
11.	Data Demonstrate Equivalence?			Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

Cannulation of the ductal system and sphincterotomy (Attachment G.

2. Device Description:

The modified Wilson-Cook OMNI™ Sphincterotome consists of a 200 cm catheter attached to a handle at the proximal end and incorporating a stainless steel cutting wire in the distal portion. The handle provides an active cord connection as well as a feature for controlling the cutting wire. The catheter has three distinct lumens: one each for the guidewire, cutting wire, and contrast medium. The catheter has separate luer hubs for guidewire and contrast medium. The distal end of the catheter has marked locations to guide the physician in correct cutting wire orientation.

Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. (Section 3, Table 1 on page 4).

Is the device life-supporting or life sustaining? **NO**

Is the device implanted (short-term or long-term)? **NO**

Does the device design use software? **NO**

Is the device sterile? **YES**

Is the device for single use? **YES**

Is the device prescription use? **YES**

Does the device contain drug or biological product as a component? **NO**

Is this device a kit? **NO**

Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

See device description above and in Section 2.0 of the application. Engineer drawing is in Attachment H and Biocompatibility data is in Attachment C.

These catheters fall into the following regulatory classification:

Trade/Device Name: Wilson-Cook OMNI™ Sphincterotome

Regulation Number: 21 CFR § 876.4300

Regulation Name: Endoscopic electricalsurgical unit and accessories

Regulatory Class: II

Product Code: KNS

**ATTACH ADDITIONAL SUPPORTING INFORMATION**

(See electronic mail dated August 4, 2005)

Device Modification	Risk	Mitigation	Verification/Validation Activity	Acceptance Criteria	Results of Verification
Tip is dome-shaped	Doming of tip may prevent flow of contrast when injected.	Design: Distal tip adequate to allow contrast flow.	Design V/V Simulated Use testing injects contrast through injection port.	Contrast should exit only through the distal tip of the catheter with no leaks at injection port observed.	All 32 test samples passed this test.
Pre-loading of wire guide into sphincterotome.	Pre-loading of wire guide may cause damage to package of OMNI™ Sphincterotome during transport, compromising sterility.	Design: Packaging designed to be such as to prevent loss of package integrity under normal shipping conditions.	Shipping Test performed per ASTM D 4169-01 <i>Performance Testing of Shipping Containers and Systems</i> for 20 total devices, 2 of which were pre-loaded with wire guide.	No visible damage to packaging or catheter visible post shipping test.	Samples of pre-loaded OMNI™ Sphincterotome met Acceptance Criteria.
Packaging sphincterotome in a racetrack holder.	Change in packaging may adversely affect device performance.	Design: Packaging designed not to introduce damaged product	<p>a. Shipping Test performed per ASTM D 4169-01 prior to V&amp;V activities.</p> <p>b. Following the Draft IFU: In anatomical position*, cannulation of the papilla was simulated by actuation of the sphincterotome handle. <i>Verification activity:</i> Verify the distal end of catheter bows between 45° and 90°.</p> <p>c. Insert preloaded device into accessory channel of endoscope. Following FS-OMNI Draft IFU, Section II, perform the following: Ensure preloaded FSW-35-185 is in the WCP and advance until exiting distal end of endoscope. <i>Verification activity:</i> Verify cutting wire orientation.</p>	<p>a. No visible damage to packaging or catheter visible post shipping test.</p> <p>b. Distal end of catheter must bow between 45° and 90° upon handle actuation.</p> <p>c. Cutting wire must orient between 11:00-1:00 during simulated use, in anatomical model.</p>	<p>a. Samples of pre-loaded OMNI™ Sphincterotome met Acceptance Criteria.</p> <p>b. All 32 samples met acceptance criteria</p> <p>c. All 32 samples met acceptance criteria</p>

Device Modification	Risk	Mitigation	Verification/Validation Activity	Acceptance Criteria	Results of Verification
(b)(4)					

Device Modification	Risk	Mitigation	Verification/Validation Activity	Acceptance Criteria	Results of Verification
(b)(4)					

(b)(4)

1.1. (b)(4)

(b)(4)

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?	N/A	
3. Have you verified that the Document is labeled Class III for GMP purposes?	✓	
4. If, not, has POS been notified?	N/A	
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	N/A	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		✓

## SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K 05 2051

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

### Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510(k)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510(k)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **	N/A	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	N/A	
510(k) Kit Certification ***	N/A	

\* - May not be applicable for Special 510(k)s.

\*\* - Required for Class III devices, only.

\*\*\* - See pages 3-12 and 3-13 in the Premarket Notification [510(k)] Manual and the Convenience Kits Interim Regulatory Guidance.

### Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	✓	
A description of the modified device and a comparison to the sponsor's predicate device.	✓	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	✓	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	✓	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	✓	
c. A Declaration of Conformity with design controls that includes the following statements:	✓	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	✓	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	✓	

**Section 3: Required Elements for an ABBREVIATED 510(k)\* submission:**

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		N/A
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.	/	
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		N/A
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

\* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

**Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):**

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	✓	
b) Sterilization and expiration dating information:	✓	
i) sterilization process	✓	
ii) validation method of sterilization process	✓	
iii) SAL	✓	
iv) packaging	N/A	
v) specify pyrogen free	✓	
vi) ETO residues	N/A	
vii) radiation dose	✓	
viii) Traditional Method or Non-Traditional Method	N/A	
c) Software Documentation:	N/A	

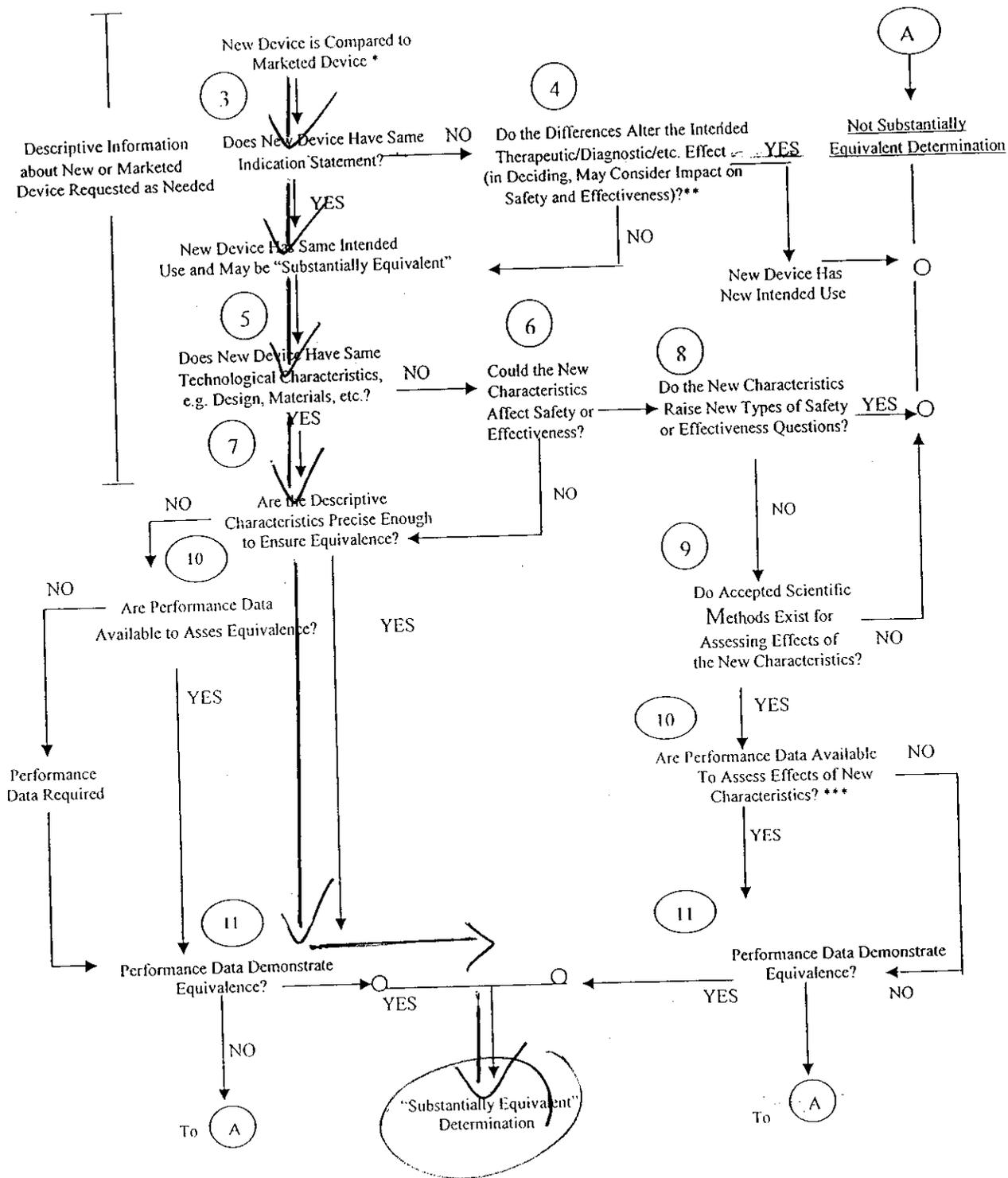
*Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.*

Passed Screening  Yes  No  
 Reviewer: Mary E. Brown, Andrew  
 Concurrence by Review Branch: \_\_\_\_\_

Date: 8/1/05

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at <http://www.fda.gov/cdrh/modact/leastburdensome.html>

### 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- \* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- \*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- \*\*\* Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.