Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

K973205

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

J. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

NOV 24 1997

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

Device Description:
The Wilson-Cook Stricture Measuring Catheter consists of a stylet wire and catheter. This device is designed for injection of contrast and to measure biliary and pancreatic strictures to determine stent size. This device is supplied sterile and is intended for single use only.

Trade Name:	Wilson-Cook Stricture Measuring Catheter
Common/Usual Name:	Stricture Measuring Catheter
Classification Name:	Catheter, Cholangiography 79 GBZ
Classification:	FDA has classified similar devices as Class I as per 21 CFR §878.4200. This device falls within the purview of the Gastroenterology and Urology Device 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 Stricture Measuring Catheter is used to measure biliary and pancreatic strictures to determine stent size through injection of contrast, and provides wire guide access.

Predicate Devices:

Wilson-Cook Glo-Tip ERCP Catheters	Wilson-Cook Medical Inc.	K851964

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

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

DEVICE CHARACTERISTIC	WILSON-COOK STRICTURE MEASURING CATHETER (Subject of 510(k))	WILSON-COOK ERCP CATHETER (K85-1964)
Intended Use	Measure biliary and pancreatic strictures, injection of contrast and provides ability to maintain wire guide access.	Injection of contrast and provides wire guide access, includes measurement system.
Stylet Material	Stainless Steel	Stainless Steel
Catheter Material	PTFE	PTFE
French Size	Catheter: 5 French	Catheter: 5-5.5 French Catheter Tip: 3-4.5 French
Catheter Length	200 cm	200 cm
Sterility	Sterile, disposable	Sterile

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

The Wilson-Cook Stricture Measuring Catheter has been tested to established performance characteristics. Samples were subjected to visual, dimensional and functional analysis. All samples were deemed acceptable, in that test specifications were met.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Exemption (b)(4); Released by CDRH on 12-29-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1997

Paula Joyce
Regulatory Affairs Manager
Wilson-Cook® Medical, Inc.
4900 Bethania Station Road
Winston-Salem, North Carolina 27105

Re: K973205
Wilson-Cook Stricture Measuring Catheter
Dated: August 25, 1997
Received: August 26, 1997
Regulatory class: II
21 CFR §876.1500/Product code: 78 KOG

Dear Ms. Joyce:

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

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

510(k) Number (if known): _____

Device Name: Wilson-Cook Stricture Measuring Catheter

Indications For Use: The Wilson-Cook Stricture Measuring Catheter is used to measure biliary and pancreatic strictures to determine stent size. This catheter allows injection of contrast and provides wire guide access to the desired duct. 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 D. Sullivan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973205

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

(Optional Format 1-2-96)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4814, released by CDRH on 12-29-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

Date: 11/26/97

From: Document Mail Center (HFZ-401)

Subject: Premarket Notification Number(s): K973205/A1

To: Division Director: G. Dorman

The attached information has been received by the 510(k) Document Mail Center (DMC), on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below. Feel free to note any additional comments below.

Thank you for your cooperation.

_____Information does not change status of the 510(k); no other action required by the DMC; please add to the image file. [THE DIVISION SHOULD PREPARE A CONFIRMATION LETTER - AN EXAMPLE IS AVAILABLE ON THE LAN (K25). THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.]

_____Additional information requires a new 510(k) however the information submitted is incomplete. Notify the company to submit a new 510(k). [THE DIVISION SHOULD PREPARE THE (K30) LETTER ON THE LAN.]

_____Additional information requires a new 510(k); please process. [THIS INFORMATION WILL BE MADE INTO A NEW 510(k)].

✓ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement or 510(k) statement).

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: Linda L Dart

Date: December 3, 1997

C. Neuland 12/3/97

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-28-2015

K973205/A1

WILSON-COOK®
MEDICAL INC.
A COOK GROUP COMPANY

RECEIVED
Nov 25 10 33 AM '97
FDA/CDRH/OCE/DMC

November 19, 1997

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: Additional Information for Wilson-Cook Stricture Measuring Catheter, K973205

Dear Ms. Dart:

As per our phone conversations on November 18th and 19th, enclosed is the requested additional information for K973205. This letter also serves to notify FDA that all correspondence regarding this 510(k) should now be directed to the undersigned, as the initial submitter of this 510(k) is no longer employed by Wilson-Cook. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Paula Joyce

Paula Joyce
Regulatory Affairs Manager

4900 Bethania Station Road
Winston-Salem, NC 27105
(910) 744-0157
Customer Service: (800) 245-4717
Office: (800) 245-4707
Fax: (910) 744-1147

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

RE: Additional Information for Wilson-Cook Stricture Measuring Catheter, K973205

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

3

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

J. <u>510(K) SUMMARY OF SAFETY AND EFFECTIVENESS</u> (continued)

[illegible]	[illegible]	[illegible]
Intended Use	Measure biliary and pancreatic strictures, injection of contrast and provides ability to maintain wire guide access.	Injection of contrast and provides wire guide access, includes measurement system.
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

WILSON-COOK®
MEDICAL INC.
A COOK GROUP COMPANY

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

K. TRUTHFUL AND ACCURATE STATEMENT
[As required by 21 CFR § 807.87(j)]

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

Paula Joyce
Regulatory Affairs Manager

November 21, 1997

4900 Bethania Station Road
Winston-Salem, NC 27105
(910) 744-0157
Customer Service: (800) 245-4717
Office: (800) 245-4707
Fax: (910) 744-1147

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Page 1 of 1 - K973205 - Released by CDRH on 12-29-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1997

Paula Joyce
Regulatory Affairs Manager
Wilson-Cook® Medical, Inc.
4900 Bethania Station Road
Winston-Salem, North Carolina 27105

Re: K973205
Wilson-Cook Stricture Measuring Catheter
Dated: August 25, 1997
Received: August 26, 1997
Regulatory class: II
21 CFR §876.1500/Product code: 78 KOG

Dear Ms. Joyce:

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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.

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Sincerely yours,

Lillian Yin

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

510(k) Number (if known): _____

Device Name: Wilson-Cook Stricture Measuring Catheter

Indications For Use: The Wilson-Cook Stricture Measuring Catheter is used to measure biliary and pancreatic strictures to determine stent size. This catheter allows injection of contrast and provides wire guide access to the desired duct. 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 D Nathan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973205

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

(Optional Format 1-2-96)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service
Food And Drug Administration

11/21/97

Memorandum

From: Reviewer(s) - Name(s) LINDA DART

Subject: 510(k) Number K973205

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

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☐ Accepted for review 9/5/97.
- ☑ 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 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Is 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

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☑ Enclosed
(required for originals received 3-14-95 and after)

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☑ The indication for use form (required for originals received 1-1-96 and after)

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 and tier: Additional Product Code(s) with panel (optional):

class II
78 KOG 876.1500 Endoscopes & accessories

Review: Carolyn Neuland, PhD (Branch Chief) GRDB (Branch Code) 11/21/97 (Date) (FWF)

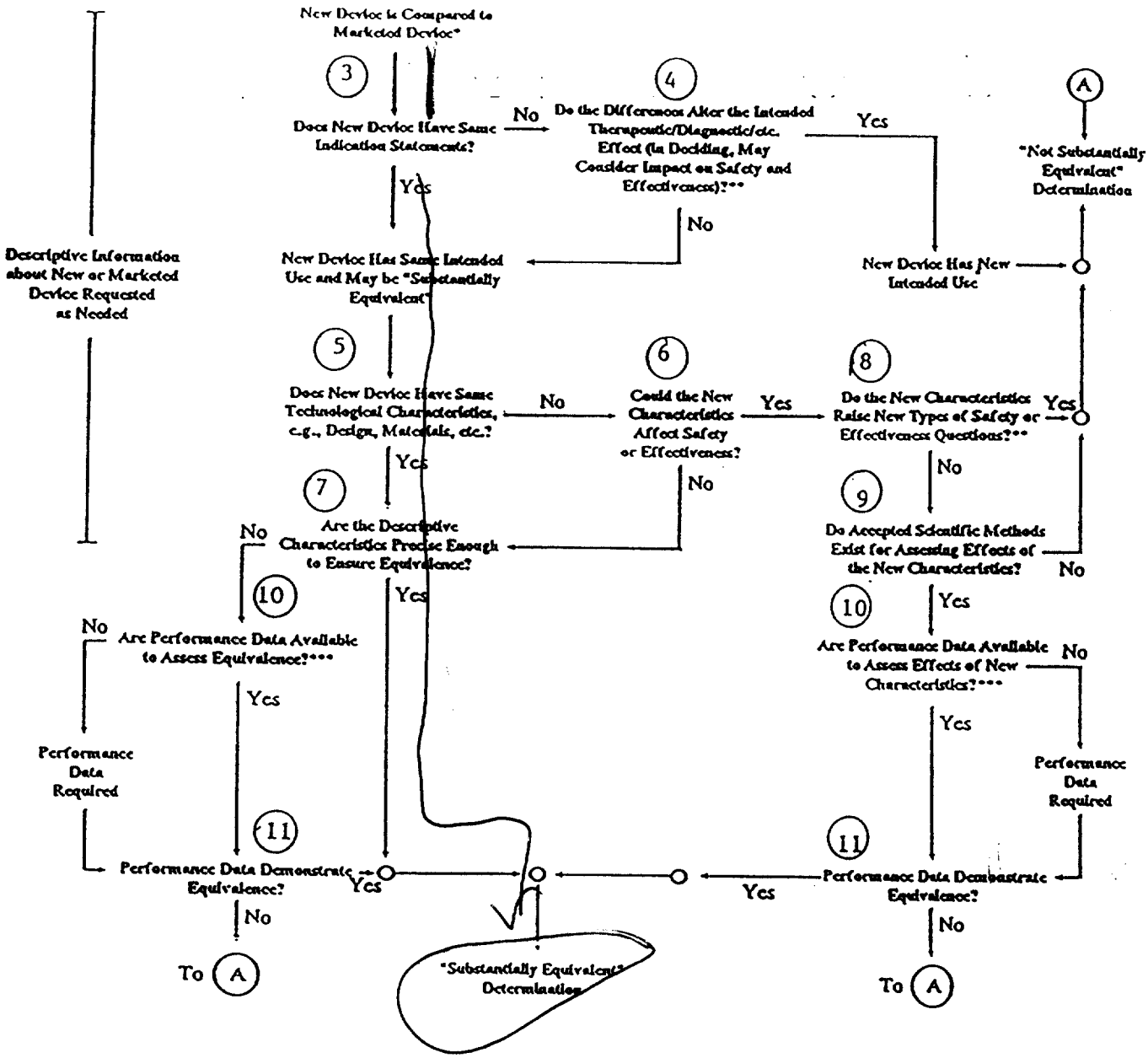
Final Review: R Lathy / L Lin (Division Director) 11/21/97 (Date)

Revised: 7/21/97

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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



- * 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 may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

MEMORANDUM

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION

DATE: November 10, 1997

FROM: Linda Dart, Biochemist
Gastrointestinal and Renal Devices Branch,
Division of Reproductive, Abdominal, ENT and Radiological Devices

SUBJECT: Wilson-Cook Medical, Inc.
Wilson-Cook Stricture Measuring Catheter
K973205

TO: The Record

Wilson-Cook Medical, Inc., has submitted a Premarket Notification (510(k)) submission for the Wilson-Cook Stricture Measuring Catheter. This device is an endoscopic retrograde cholangiographic/pancreatographic (ERCP) catheter indicated for use in introducing contrast media into biliary and/or pancreatic ducts and for measuring biliary and pancreatic strictures to determine stent size.

Device description

The Wilson-Cook Stricture Measuring Device is a catheter for introducing contrast media into biliary and/or pancreatic ducts. In addition, once the catheter has been placed in a duct, radiopaque marks on the tip of the device allows the user to measure an area of stricture and then allows guidewire access to the stricture (through the lumen of the catheter) for the introduction of one or more biliary/pancreatic stents to the strictured area.

The device consists of a stylet wire and a catheter with radiopaque markings. The stylet is made of stainless steel and the catheter is composed of polytetrafluoroethylene (PTFE). The firm indicates that as PTFE is used in similar predicate devices, such as the Wilson-Cook Glo-Tip ERCP catheter (K851964) , there is a reasonable assurance of biocompatibility of all materials established through their history of use in medical devices. Although these statements concerning PTFE may be correct, it has not been established that all PTFEs are equivalent. **I have discussed this concern with Ms. Paula Joyce of Wilson-Cook (teleconference November 18, 1997) and I have asked her to provide, 1) information concerning the exact PTFE used in the**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

stricture measuring catheter and , 2) a statement certifying that this PTFE is the identical PTFE used in a legally marketed predicate device, (i.e., Wilson-Cook Glo-Tip ERCP catheter (K851964)). I also noted we have the same concerns with the radiopaque markers on the tip of the stricture measuring catheter and we will need Wilson-Cook to identify the specific materials used for the markings and provide a certification statement noting the identical materials are used in a predicate device (which they will also need to identify). As the stainless steel stylet is not a patient contacting material, we do not require further biocompatibility information for this component of the device.

The device is introduced into the biliary/pancreatic duct system endoscopically. The catheter is 5 French in diameter. **I talked to Ms. Joyce on November 19, 1997, to clarify discrepancies concerning the length of the catheter. For instance, on page 2 of this 510(k) submission, the length is listed as 200 cm, while on page 11 (510(k) Summary information), the length is listed as 100 cm. As noted below (510(k) Summary information) the length noted in the 510(k) Summary of Safety and Effectiveness is incorrect, the actual length of the catheter is 200 cm. Ms Joyce has told me that the materials used in the radiopaque marks is tantalum. She explained that as these markers are beneath the surface of the catheter, they will not be patient contacting and therefore, no biocompatibility information will be provided. Ms. Joyce will provide a statement concerning the material used in the markers and the reason biocompatibility information is not included for the submission..**

Label

The device is available by prescription only. It is labeled for single use only , is disposable and is provided sterile by ethylene oxide (EtO) with an SAL of 10^{-6}. Validation of the EtO cycle is by the "Overkill Method" as per AAMI standards. EtO residuals limits will be verified to be less than 250 ppm for EtO, 250 ppm for Ethylene Chlorhydrin and 5000 ppm for Ethylene Glycol. The device (catheter and stylet) are packaged in a Tyvek® and Mylar pouch to ensure that sterility is maintained. Instructions for resterilizing the device in the event that the package is inadvertently opened has been provided. **I questioned whether the performance testing on the device had included devices that had been resterilized. Ms Joyce explained that all bench testing was performed using devices which had been through 3 cycles of sterilization. Ms. Joyce will provide a statement to this effect for the submission.**

Instructions for use have been included and appear to be adequate. Contraindications noted are those specific to ERCP procedures. Instructions for using a guidewire with the catheter are provided. Although no guidewire is provided with the device, it is recommended in the instructions for use that Wilson-Cook guidewires be used and it is noted that Wilson-Cook guidewires are color-coded with the device to aid the user.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

Performance testing

Functional testing was conducted to determine performance characteristics and design integrity. Testing is stated to include visual, dimensional, and functional analysis of 32 post-sterile finished products. All samples tested were deemed to be acceptable.

Similarities and Differences with predicate device

Device Characteristics	Wilson-Cook Stricture Measuring Catheter	Wilson -Cook ERCP Catheter K851964	Wilson-Cook ERCP Catheter K932205
Intended Use	Inject contrast media into biliary/pancreatic ducts. Measure biliary and pancreatic strictures. Provide the ability to maintain guidewire access	Inject contrast media into biliary/pancreatic ducts.	Inject contrast media into biliary/pancreatic ducts. Provide Guidewire access to ducts. Visualized measuring system.
Catheter material	Polytetrafluoro-ethylene (PTFE)	PTFE	PTFE with hydrophilic coating
Catheter diameter	5 FR	5 FR	5 - 5.5 FR
Catheter length	200 cm	200 cm	200 cm
Stylet material	.020" 304-stainless steel	.020" 304-stainless steel	0.20" 304-stainless steel
Guidewire access	Yes	No	Yes
Visualization system	Yes - fluoroscopic	No	Yes-endoscopic and fluoroscopic
Placement	Endoscopic	Endoscopic	Endoscopic

510(k) Summary of Safety and Effectiveness

A 510(k) Summary of Safety and Effectiveness has been provided, however, the length noted for the catheter in this summary (100 cm) differs from the length noted in the device description provided on page 2 of the submission (200 cm). **In a teleconference with Ms. Joyce on November 19, 1997, she explained that the information provided in the summary was incorrect. Ms Joyce noted she would include a new copy of the summary with the correct information.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

Indication for Use statement

The separate statement identifying the indication for use of the device has been provided and is adequate.

Truthful and Accurate Statement

A statement certifying that all data and information submitted in this 510(K) submission are truthful and accurate has been provided., however, the person who has signed this form for Wilson-Cook Medical, is no longer with the firm. **Ms Joyce will supply a new certification statement signed by a person in authority position within the firm.**

RECOMMENDATION:

As soon as the above information is received, I recommend the Wilson-Cook Stricture Measuring Catheter be found substantially equivalent to ERCP catheters (procode 78 KOG). a Class II device as described in 21 CFR part §876.1500, Endoscopes and accessories.

Linda L. Dart

Linda L. Dart

C. Herland
11/21/97

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

K973205 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENT

REVIEWER: Linda Dart DIVISION/BRANCH: DRAERD/GRDB
Wilson-Cook
TRADE NAME: Stricture Measuring Catheter COMMON NAME: Cholangiography catheter

PRODUCT TO WHICH COMPARED: Wilson-Cook ERCP Catheters

(510(k) NUMBER IF KNOWN) K851964, K932205

	YES	NO	
1. IS PRODUCT A DEVICE?	X	_	- IF NO STOP
2. 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?	_	_	- IF YES STOP - NSE
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 - SE
9. ACCEPTED SCIENTIFIC METHODS EXIST?	_	_	- IF NO STOP - SE
10. PERFORMANCE DATA AVAILABLE?	_	_	- IF NO REQUEST DATA
11.*DATA DEMONSTRATE EQUIVALENCE?	_	_	

NOTE: IN ADDITION TO COMPLETING PAGE 2, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY NO RESPONSE REQUIRES AN EXPLANATION ON PAGE 3 AND/OR 4.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE:

Introduction of contrast media, maintaining wire guide access, and measuring strictures in biliary and/or pancreatic ducts.

2. DEVICE DESCRIPTION: 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. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life-sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological products as components? Is this device a kit? Provide a summary about the device's design, materials, physical properties and toxicology profile if important.

SUMMARY:

The Wilson-Cook Stricture Measuring Device is a catheter for introducing contrast media into biliary and/or pancreatic ducts. In addition, once the catheter has been placed in a duct, radiopaque marks on the tip of the device allows the user to measure an area of stricture and then allows guidewire access to the stricture (through the lumen of the catheter) for the introduction of one or more biliary/pancreatic stents to the strictured area.

The device consists of a stylet wire and a catheter with radiopaque markings. The stylet is made of stainless steel (304-stainless steel) and the catheter is composed of polytetrafluoroethylene (PTFE) . The radiopaque markers are made of tantalum. The PTFE is the only material stated to be in patient contact. A statement certifying that the PTFE used in the device is the same material as is used in similar devices legally marketed in the United States has been provided. Both the tantalum and stainless steel are described as non-patient contacting. Therefore, no biocompatibility data is necessary.

The device is introduced into the biliary/pancreatic duct system endoscopically. The catheter is 5 French in diameter and 200 cm in length. There are 15 radiopaque marks placed 1 cm apart, along a line which runs the length of the catheter tip. These radiopaque markers allow the user to measure a strictured area in the biliary/pancreatic duct(s).

The device is available by prescription only. It is labeled for single use only , is disposable and is provided sterile by ethylene oxide (EtO) with an SAL of 10^{-6}. Validation of the EtO cycle is by the "Overkill Method" as per AAMI standards. EtO residuals limits will be verified to be less than 250 ppm for EtO, 250 ppm for Ethylene Chlorhydrin and 5000 ppm for Ethylene Glycol. The device (catheter and stylet) are packaged in a Tyvek® and Mylar pouch to ensure that sterility is maintained.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Instructions for use have been included and appear to be adequate. Contraindications noted are those specific to ERCP procedures. Instructions for using a guidewire with the catheter are provided. Although no guidewire is provided with the device, it is recommended in the instructions for use that Wilson-Cook guidewires be used and it is noted that Wilson-Cook guidewires are color-coded with the device to aid the user.

Functional testing was conducted to determine performance characteristics and design integrity. Testing which included visual, dimensional, and functional analysis was performed on 32 post-sterile finished products. All samples tested were deemed to be acceptable. .

Instructions for resterilizing the device in the event that the package is inadvertently opened has been provided. The firm notes that bench testing was performed using devices which had been through a maximum of 3 cycles of sterilization validation. Therefore, the single resterilization by the user in such an event (inadvertent opening of package) should not alter the substantial equivalence of the device.

Similarities and Differences with predicate device

Device Characteristics	Wilson-Cook Stricture Measuring Catheter	Wilson -Cook ERCP Catheter K851964	Wilson-Cook ERCP Catheter K932205
Intended Use	Inject contrast media into biliary/pancreatic ducts. Measure biliary and pancreatic strictures. Provide the ability to maintain guidewire access	Inject contrast media into biliary/pancreatic ducts.	Inject contrast media into biliary/pancreatic ducts. Provide Guidewire access to ducts. Visualized measuring system.
Catheter material	Polytetrafluoro-ethylene (PTFE)	PTFE	PTFE with hydrophilic coating
Catheter diameter	5 FR	5 FR	5 - 5.5 FR
Catheter length	200 cm	200 cm	200 cm
Stylet material	.020" 304-stainless steel	.020" 304-stainless steel	0.20" 304-stainless steel
Guidewire access	Yes	No	Yes
Visualization system	Yes - fluoroscopic	No	Yes-endoscopic and fluoroscopic
Placement	Endoscopic	Endoscopic	Endoscopic

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	YES	NO
1. Is the device life-supporting or life sustaining?		X
2. Is the device implanted (short-term or long-term)?	X	
3. Is the device software-driven?		X
4. Is the device sterile?	X	
5. Is the device for single use?	X	
6. Is the device for home use?		X
7. Is the device for prescription use?	X	
8. Does the device contain a drug or biological?		X

EXPLANATIONS TO "YES" AND "NO" ANSWER TO QUESTIONS ON PAGE 1 AS NEEDED

1. EXPLAIN WHY NOT A DEVICE:

2. EXPLAIN WHY NOT SUBJECT TO A 510(K):

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION:

4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE:

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS:

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS:

7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH:

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

9. EXPLAIN WHY EXISTING SCIENTIFIC METHODS CAN NOT BE USED:

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED:

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT:

Recommendation:

Substantially equivalent to other endoscopic accessories (procode 78 KOG), Class II devices as described in 21 CFR part §876.1500, Endoscopes and accessories.

Linda L. Dart

Linda L. Dart

C. Neuland
11/21/97

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

4900 Bethania Station Road
Winston-Salem, NC 27105
Phone: 800-245-4707
Fax: (910) 767-2657

Wilson-Cook Medical Inc.

Fax

To:	Ms. Linda Dart –FDA ODE	**From:**	Paula Joyce
Fax:	(301) 594-2339	**Date:**	November 21, 1997
Phone:		**Pages:**	6
Re:	**Requested Additional Information for K973205**	**CC:**	

☐ **Urgent** x **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

•Comments:

Dear Ms. Dart:

Attached for your review is the response to your concerns regarding our Stricture Measuring Catheter 510(k) (K973205). Please note that a statement regarding the correspondent at Wilson-Cook for this submission is addressed in the cover letter, which accompanies the additional information. Should you have any questions, please do not hesitate to contact me

Sincerely,

Paula Joyce

Paula Joyce

Regulatory Affairs Manager

To be followed by hard copy.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

TO: Ms. Linda Dart - FDA, ODE
FROM: Paula Joyce
Page 2 of 6

WILSON-COOK®
MEDICAL INC.
A COOK GROUP COMPANY

November 19, 1997

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: Additional Information for Wilson-Cook Stricture Measuring Catheter, K973205

Dear Ms. Dart:

As per our phone conversations on November 18th and 19th, enclosed is the requested additional information for K973205. This letter also serves to notify FDA that all correspondence regarding this 510(k) should now be directed to the undersigned, as the initial submitter of this 510(k) is no longer employed by Wilson-Cook. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Paula Joyce

Paula Joyce
Regulatory Affairs Manager

4900 Bethania Station Road
Winston-Salem, NC 27105
(910) 744-0157
Customer Service: (800) 245-4717
Office: (800) 245-4707
Fax: (910) 744-1147

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015
TO: Linda Dan - FDA/CDRH FROM: FOIA Joyce Page 3 of 6

RE: Additional Information for Wilson-Cook Stricture Measuring Catheter, K973205

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-4214; Released by CDRH on 12-29-2015
TO: Linda Bahn - FDA OCE FROM: Maria Joyce Page 4 of 6

RE: Additional Information for Wilson-Cook Stricture Measuring Catheter, K973205

(b) (4)

[redacted]

Records processed under FOIA Request #2015-4314; Released by CDRH on 12-29-2015

TO: Linda Bast - FDA CDRH
FROM: Paula Joyce

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

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

DEVICE CHARACTERISTIC	WILSON-COOK STRICTURE MEASURING CATHETER [Subject of 510(k)]	WILSON-COOK ERCP CATHETER (K85196)
Intended Use	Measure biliary and pancreatic strictures, injection of contrast and provides ability to maintain wire guide access.	Injection of contrast and provides wire guide access, includes measurement system.
Stylet Material	Stainless Steel	Stainless Steel
Catheter Material	PTFE	PTFE
French Size	Catheter: 5 French	Catheter: 5-5.5 French Catheter Tip: 3-4.5 French
Catheter Length	200 cm	200 cm
Sterility	Sterile, disposable	Sterile

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

The Wilson-Cook Stricture Measuring Catheter has been tested to established performance characteristics. Samples were subjected to visual, dimensional and functional analysis. All samples were deemed acceptable, in that test specifications were met

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Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

TO: Linda Dart

FROM: Paula Joyce

WILSON-COOK®
MEDICAL INC.
A COOK GROUP COMPANY

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

K. TRUTHFUL AND ACCURATE STATEMENT
[As required by 21 CFR § 807.87(j)]

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

Paula Joyce
Regulatory Affairs Manager

November 21, 1997

4900 Bethania Station Road
Winston-Salem, NC 27105
(910) 744-0157
Customer Service: (800) 245-4717
Office: (800) 245-4707
Fax: (910) 744-1147

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

0RRG/LLD 1/6/93
Rev. 2/6/96

DRAERD Premarket Notification 510(k) Screening Checklist

510(k) Number & Device Name K974018 Wilson-Cook 10 Shot Multi-band Ligator

Company Wilson-Cook Medical, Inc.

ITEM	PRESENT Yes	PRESENT No	NEEDED (Y/N/?)
1. General information (i.e., trade & classification name, Est. Reg. No., device class, meets special controls or a performance standards, etc.)	✓	—	—
Reason for 510(k) - new device or modification	✓	—	—
Identification of legally marketed equivalent device	✓	—	—
Truthful and accurate statement	✓	—	—
SMDA 510(k) summary or statement	✓	—	—
2. Proposed Labeling, Labels, Advertisements	✓	—	—
Description of new device/modification	✓	—	—
Intended use statement	✓	—	—
Diagrams, Engineering Drawings, Photographs	✓	—	—
Indication for Use Statement	✓	—	—
3. Comparison of similarities/differences to named legally marketed equivalent device	✓	—	—
Equivalent Device Labeling, Labels, Advertising	✓	—	—
Intended use of equivalent device	✓	—	—
4. List of all patient contacting materials in new device	✓	—	—
Comparison of materials to equivalent device	✓	—	—
5. Biocompatibility information/data for patient contacting materials, OR	✓	—	—
Certification - identical material/formulation	✓	—	—
6. Performance data: Bench data	✓	—	—
Animal data	—	✓	N
Clinical data	—	✓	N
7. Sterilization information	—	✓	N
8. Software validation & verification	—	✓	N
9. If Class III, Class III Certification & Summary	—	✓	N
10. If kit, kit certification	—	✓	N

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

FOR REVIEWER'S USE ONLY

RRG 9/24/93
Rev. 5/8/95

DRAERD Premarket Notification 510(k)
SUPPLEMENTAL Screening Checklist

DRAERD has been given the go ahead to continue with the DRAERD Premarket Notification 510(k) Screening Checklist program rather than switching to the ODE Premarket Notification (510(k)) Checklist for Acceptance Decision. However, some items appear in the ODE Checklist that were not in the early version of the DRAERD Checklist or Explanation of the Checklist. Therefore, the following items should be included as part of the DRAERD screening process:

510(k) Number: K973205 TIER (Circle) I

Expedited Review Requested: N Granted: N OR, FDA Identified Expedited: N

ITEM	Yes	No
1. Is the product a device?	✓	
2. Is the device exempt from 510(k) by regulation or policy?		✓
3. Are you aware that this device has been the subject of a previous NSE decision?		✓
If yes, does this new 510(k) address the NSE Issue(s) (e.g., performance data)?		N/A
4. Are you aware of the submitter being the subject of an integrity investigation?		✓
If yes, consult the ODE Integrity Officer, and has the ODE Integrity Officer given permission to proceed with the review?		N/A
5. Is there a specific guidance document for this device or device issue(s)?		✓
6. Is this a file that was determined to be substantially equivalent (SE) by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? If yes, a new review by ODE is not required, please forward to POS.		✓

In addition, the following item is going to be required as part of a revision to the 510(k) regulation. However, it is not required now, but the Explanation of the DRAERD Screening Checklist has been modified to include this information.

7. Address of manufacturing facility/facilities, and if applicable, sterilization site(s).		✓

Administrative Reviewer Signature: Linda L Dart Date: 9/5/97

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

REVISED:01/22/96

PREMARKET NOTIFICATION (510(K)) CHECKLIST FOR ACCEPTANCE DECISION

K_____ Device Name_____

Division/Branch_____

Administrative Reviewer Signature_____Date_____

Supervisory Signature_____Date_____

Did the firm request expedited review? _____Yes_____No

Did we grant expedited review? _____Yes_____No

Truthful and accurate statement enclosed?_____Yes_____No
(If Not Enclosed, Must Be A Refuse To Accept Letter)
Required For Originals Received 3/14/95 And After

Is the Indication for Use Form enclosed?_____YES_____No
(Required for Original 510(k)s received 1/1/96 and after -- must be submitted on a separate sheet of paper)

Without reviewing this 510(k), do you believe this device type may be a preamendments class III device? _____Yes_____No (IF YES, NOTIFY POS IMMEDIATELY IF THE OUTSIDE OF THE 510(k) HAS NOT BEEN STAMPED CLASS III SO THAT THE GMP INSPECTION CAN BE SCHEDULED AS SOON AS POSSIBLE). Class III devices can not receive a determination of substantial equivalence until the GMP inspection process has been completed.

Is this a file that was determined to be substantially equivalent by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? If so, a new ODE review is not required, please forward to POS.

_____Yes _____No

_____ Accepted

_____ Refuse To Accept

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

CRITICAL ELEMENTS:	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
A. Is The Product A Device?	☐	☐
B. Is The Device Exempt From 510(k) By Regulation Or Policy?	☐	☐
C. Is Device Subject To Review By CDRH?	☐	☐
D. (i) Are You Aware That This Device Has Been The Subject Of A Previous NSE Decision?	☐	☐
(ii) If Yes, Does This New 510(k) Address The NSE Issue(s) (E.G., Performance Data)?	☐	☐
E. (i) Are You Aware Of The Submitter Being The Subject Of An Integrity Investigation? If Yes, Consult The ODE Integrity Officer.	☐	☐
(ii) Has The ODE Integrity Officer Given Permission To Proceed With The Review? (Blue Book Memo #I91-2 And Federal Register 90N-0332, September 10, 1991.)	☐	☐
. Does The Submission Contain The Information Required Under Sections 510(k), 513(f), And 513(i) Of The Federal Food, Drug, and Cosmetic Act (Act) And Subpart E Of Part 807 In Title 21 Of The Code Of Federal Regulations?:	☐	☐
1. Device Trade Or Proprietary Name	☐	☐
2. Device Common Or Usual Name Or Classification Name	☐	☐
3. Establishment Registration Number (Only Applies If Establishment Is Registered)	☐	☐
4. Class Into Which The Device Is Classified Under (21 CFR Parts 862 to 892)	☐	☐
5. Classification Panel	☐	☐
6. Action Taken To Comply With Section 514 Of The Act	☐	☐
7. Proposed Labels, Labeling And Advertisements (If Available) That Describe The Device, Its Intended Use, And Directions For Use (Blue Book Memo #G91-1)	☐	☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

8. A 510(k) Summary Of Safety And Effectiveness Or A 510(k) Statement That Safety And Effectiveness Information Will Be Made Available To Any Person Upon Request	☐	☐
9. For Class III Devices Only, A Class III Certification And A Class III Summary	☐	☐
10. Photographs Of The Device	☐	☐
11. Engineering Drawings For The Device With Dimensions And Tolerances	☐	☐
12. The Marketed Device(s) To Which Equivalence Is Claimed Including Labeling And Description Of The Device	☐	☐
13. Statement Of Similarities And/Or Differences With Marketed Device(s)	☐	☐
14. Data To Show Consequences And Effects Of A Modified Device(s)	☐	☐
15. Truthful And Accurate Statement	☐	☐
II. Additional Information That Is Necessary Under 21 CFR 807.87(h):	☐	☐
A. Submitter's Name And Address	☐	☐
B. Contact Person, Telephone Number And Fax Number	☐	☐
C. Representative/Consultant If Applicable	☐	☐
D. Table Of Contents With Pagination	☐	☐
E. Address Of Manufacturing Facility/Facilities And, If Appropriate, Sterilization Site(s)	☐	☐
III. Additional Information That May Be Necessary Under 21 CFR 807.87(h):	☐	☐
A. Comparison Table Of The New Device To The Marketed Device(s)	☐	☐
B. Action Taken To Comply With Voluntary Standards	☐	☐
C. Performance Data	☐	☐
MARKETED DEVICE:	☐	☐
Bench Testing	☐	☐
Animal Testing	☐	☐
Clinical Data	☐	☐
NEW DEVICE:	☐	☐
Bench Testing	☐	☐
Animal Testing	☐	☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

	Clinical Data	☐	☐
	Sterilization Information	☐	☐
	Software Information	☐	☐
F.	Hardware Information	☐	☐
G.	If This 510(k) Is For A Kit, Has The Kit Certification Statement Been Provided?	☐	☐
H.	Is This Device Subject To Issues That Have Been Addressed In Specific Guidance Document(s)?	☐	☐
	If Yes, Continue Review With Checklist From Any Appropriate Guidance Documents.	☐	☐
	If No, Is 510(k) Sufficiently Complete To Allow Substantive Review?	☐	☐
I.	Other (Specify)	☐	☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

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

K_____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			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:

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

1. Intended Use:

2. Device Description: 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. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics ar not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

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

August 27, 1997

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

510(k) Number: K973205
Received: 26-AUG-97
Product: WILSON-COOK STRICTURE MEASURING CATHETER

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), 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 January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA 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
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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WILSON-COOK®
MEDICAL INC.
A COOK GROUP COMPANY

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26 AUG 97 11 14
FDA/CDRH/OCE/DHC

August 25, 1997

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 THE WILSON-COOK STRICTURE MEASURING CATHETER

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 Stricture Measuring Catheter.

The following information is submitted pertaining to the Wilson-Cook Stricture Measuring Catheter:

1. **Classification Name:** Catheter, Cholangiography; 79 GBZ

2. **Classification:** FDA has classified similar devices as Class I as [redacted]r 21 CFR § 878.4200. This device falls within the purview of the Gastroenterology and Urology Device Panel.

3. **Trade Name/Proprietary Name:** Wilson-Cook Stricture Measuring Catheter

4. **Common/Usual Name:** Stricture Measuring Catheter

5. **Establishment Registration Number:** 1037905

4900 Bethania Station Road
Winston-Salem, NC 27105
10) 744-0157
Customer Service: (800) 245-4717
Office: (800) 245-4707
Fax: (910) 744-1141

GU
Class I

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING CATHETER

6. No performance standards applicable to gastroenterology-urology introduction/drainage catheter and accessories have been established by the Food and Drug Administration.

7. Draft packaging labeling and instructions for use are included as **Attachment I**.

8. This device is similar with respect to technological characteristics and intended use to predicate ERCP catheters, including Wilson-Cook Glo-Tip ERCP Catheters. Refer to **Table I** for a complete device comparison and to **Attachment II** for literature and instructions for use for the referenced predicate device.

PREDICATE DEVICE	COMPANY	510(K) NUMBER
Wilson-Cook Glo-Tip ERCP Catheters	Wilson-Cook Medical Inc.	K851964

9. Refer to **Sections B through I** for information describing the Wilson-Cook Stricture Measuring Catheter.

10. The intended use statement is included in **Section A.**

11. The 510(k) Safety and Effectiveness Summary is included as **Section J** of this submission.

12. The Truthful and Accurate statement, as required by 21 CFR § 807.87(j) is included in **Section K** of this submission.

13. Intended Use statement is included as **Attachment III**.

Wilson-Cook considers its' intent to manufacturer and market this product as confidential, commercial information, and we request that it be considered as such by FDA, and not be made available through Freedom of Information except where required by law. Should there be any questions pertaining to this submission, please do not hesitate to contact me.

Sincerely,

Sophia Rouse

Sophia Rouse
Regulatory Affairs Specialist

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PREMARKET NOTIFICATION

WILSON-COOK STRICTURE MEASURING CATHETER

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FIGURE

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ATTACHMENTS

Attachment I – Draft Packaging labeling and Instructions for use

Attachment II – Instructions for use for predicate device

Attachment III - Intended Use Statement

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

A. INTENDED USE

The Wilson-Cook Stricture Measuring Catheter is used to measure biliary and pancreatic strictures to determine stent size. This catheter allows injection of contrast and provides wire guide access to the desired duct. This device is supplied sterile and is intended for single use only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

B. PHYSICAL COMPOSITION

The Wilson-Cook Stricture Measuring Catheter consists of a stylet wire, and a catheter for measuring. An engineering drawing for this product is included in **Figure 1** on page 3 of this submission. The list of materials for all patient contacting components is as follows:

PATIENT CONTACTING COMPONENTS

[illegible]	[illegible]
Catheter	Polytetrafluoroethylene

All non-patient contacting components are comprised of materials commonly used in other Wilson-Cook predicate devices including Wilson-Cook ERCP Catheters (K851964).

C. BIOCOMPATIBILITY

Reasonable assurance of biocompatibility of all construction materials has been established through their history of use in medical devices. Identical materials including Polytetrafluoroethylene are used in similar predicate devices. It is hereby certified that Wilson-Cook Medical uses identical materials in predicate devices used in the biliary and pancreatic systems. Among those predicate devices are the Wilson-Cook Glo-Tip ERCP Catheter. These predicate devices were cleared to market in June 1985, as per K851964.

D. SPECIFICATIONS

The Wilson-Cook Stricture Measuring Catheter is manufactured by Wilson-Cook Medical. Throughout manufacturing, trained production and quality control inspectors follow standard operating procedures adhering to current Quality Systems Regulations providing reasonable assurance that the device will perform its intended function with safety and consistency. Specifications for this device are as per the following table:

WILSON-COOK STRICTURE MEASURING CATHETER

Catheter Size	[illegible]	[illegible]
5.0	200 cm	100 cm

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4)

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RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

E. PACKAGING

The Wilson-Cook Stricture Measuring Catheter is packaged in a Tyvek® and Mylar® pouch.

F. STERILIZATION

The Wilson-Cook Stricture Measuring Catheter is supplied in a sterile peel-open pouch. This device is sterilized using a validated ethylene oxide gas cycle, obtaining an SAL of 10^{-6}. Validation follows the "Overkill Method" as stated in the AAMI Standard 11135-*Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*. The EO residual limits will be verified to be less than the maximum levels established for this device. The maximum levels (proposed by 43 Federal Register 27482, June 23, 1978) are for devices contacting mucosa and are as follows:

Ethylene Oxide	Ethylene Chlorhydrin	Ethylene Glycol
< 250 ppm	< 250 ppm	< 5000 ppm

G. METHOD OF OPERATION

The Wilson-Cook Stricture Measuring Device is designed to measure biliary and pancreatic strictures to determine stent size. This catheter allows injection of contrast and provides the ability to maintain wire guide access to the desired duct for the introduction of compatible devices

Advance the stylet completely into the Stricture Measuring Catheter. Lock the stylet cap into the catheter fitting. Introduce the catheter into the endoscope and advance, in short increments, until the device is endoscopically visualized exiting the scope. Contrast may be injected to fluoroscopically confirm the position of the device. The tip of the Stricture Measuring Catheter has radiopaque bands at 1 cm intervals in order to measure the stricture and determine the appropriate stent size. A wire guide may be used with the Stricture Measuring Catheter. Remove the stylet from the catheter and advance a compatible wire guide prior to removing the catheter from the endoscope

H. SUBSTANTIAL EQUIVALENCE

The Wilson-Cook Stricture Measuring Catheter is virtually identical to the predicate device with respect to design, materials and intended use. This device combines the technological characteristics and intended use of predicate devices, allowing endoscopic cannulation of the ductal system. **Table I** follows, including a complete product comparison:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

H. SUBSTANTIAL EQUIVALENCE (continued)

TABLE I - PRODUCT COMPARISON

DEVICE CHARACTERISTICS	[illegible]	[illegible]
Intended Use	Measure biliary and pancreatic strictures; injection of contrast and provides the ability to maintain wire guide access.	Injection of contrast and provides wire guide access; visualized measurement system
Stylet	Stainless Steel	Stainless Steel
Catheter	Polytetrafluoroethylene	Polytetrafluoroethylene
French Size	Catheter: 5.0	Catheter: 5.0 - 5.5 Catheter Tip: 3.0 – 4.5
Length	100 cm	100 cm
Sterility	Sterile, disposable	Sterile, disposable

The materials of construction for the Stricture Measuring Catheter are identical to the materials of construction for the predicate device. The design differences include minor dimensional catheter French sizes. The predicate devices include markings to assist in determination of stent length, which is an endoscopically or fluoroscopically visualized measurement system used to determine the stent length and to verify cannulation depth. Both the Stricture Measuring Catheter and the predicate devices allow injection of contrast.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

PRODUCT FUNCTIONAL TESTING

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

I. FUNCTIONAL TESTING (continued)

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

I. FUNCTIONAL TESTING (continued)

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

I. FUNCTIONAL TESTING (continued)

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

J. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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

Device Description:
The Wilson-Cook Stricture Measuring Catheter consists of a stylet wire and catheter. This device is designed for injection of contrast and to measure biliary and pancreatic strictures to determine stent size. This device is supplied sterile and is intended for single use only.

Trade Name:	Wilson-Cook Stricture Measuring Catheter
Common/Usual Name:	Stricture Measuring Catheter
Classification Name:	Catheter, Cholangiography 79 GBZ
Classification:	FDA has classified similar devices as Class I as per 21 CFR §878.4200. This device falls within the purview of the Gastroenterology and Urology Device 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 Stricture Measuring Catheter is used to measure biliary and pancreatic strictures to determine stent size through injection of contrast, and provides wire guide access.

Predicate Devices:

PREDICATE DEVICE	MANUFACTURER	510(K) NUMBER
Wilson-Cook Glo-Tip ERCP Catheters	Wilson-Cook Medical Inc.	K851964

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

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

DEVICE CHARACTERISTIC	WILSON-COOK [illegible] (K[illegible])	WILSON-COOK [illegible] (K[illegible])
Intended Use	Measure biliary and pancreatic strictures: injection of contrast and provides the ability to maintain wire guide access.	Injection of contrast and provides wire guide access; visualized measurement system
Stylet	Stainless Steel	Stainless Steel
Catheter	Polytetrafluoroethylene	Polytetrafluoroethylene
French Size	Catheter: 5.0	Catheter: 5.0 - 5.5 Catheter Tip: 3.0 – 4.5
Length	100 cm	100 cm
Sterility	Sterile, disposable	Sterile, disposable

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

The Wilson-Cook Stricture Measuring Catheter has been tested to establish performance characteristics. Samples were subjected to visual, dimensional and functional analysis All samples were deemed acceptable, in that test specifications were met.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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WILSON-COOK®
MEDICAL INC.
A COOK GROUP COMPANY

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK STRICTURE MEASURING DEVICE

K. TRUTHFUL AND ACCURATE STATEMENT
[As required by 21 CFR §807.87 (j)]

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

Sophia Rouse

Sophia Rouse

August 25, 1997

4900 Bethania Station Road
Winston-Salem, NC 27105
(910) 384-2157
Customer Service (800) 245-4717
Office (910) 245-4707
Fax (910) 384-2174

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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STERILIZATION DATE DATE de la STÉRILISATION DATUM DER STERILISIERUNG FECHA DE ESTERILIZACION	EXPIRY DATE DATE D'EXPIRATION VERFALLSDATUM FECHA DE EXPIRACION	BATCH NUMBER NUMÉRO DU GROUPE GRUPPENNUMMER NUMERO DE LOTE
XXX	XXX	XXX

STERILE

SMC-1

ERCP CATHETER

5 FR. TEFLON 200 CM., STYLET WIRE,
ACCEPTS .035" WIRE GUIDE.
DISPOSABLE - SINGLE USE ONLY

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. STERILE if package is unopened and undamaged. Made in USA.

11/95

WILSON-COOK® MEDICAL INC.
A COOK GROUP COMPANY

4900 Bethania Station Road • Winston-Salem, NC 27105

Patient Charge

Reorder No.: SMC-1
Lot No.: *XXXX*
Description: ERCP CATHETER

WILSON-COOK® MEDICAL INC.

Inventory

Reorder No.: SMC-1
Lot No.: *XXXX*
Description: ERCP CATHETER

WILSON-COOK® MEDICAL INC.

Patient Chart

Reorder No.: SMC-1
Lot No.: *XXXX*
Description: ERCP CATHETER

WILSON-COOK® MEDICAL INC.

+H791368510

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

yd

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5/19/97- DRAFT

Stricture Measuring Catheter

IMPORTANT INFORMATION
Please Review Prior to Use.

INTENDED USE

The Stricture Measuring Catheter is used to measure biliary and pancreatic strictures to determine stent size. This catheter allows injection of contrast and provides the ability to maintain wire guide access to the desired duct for the introduction of compatible devices. This device is supplied sterile and is intended for single use only. (D icon)

NOTES

To ensure these instructions are current, please contact Customer Service if the purchase date of this product has exceeded two years.

Do not use this device for any purpose other than the stated intended use.

Inventory rotation of sterile products is essential. Verify the expiration date on the package label prior to using the product. If the expiration date has lapsed, do not use or resterilize the device.

If the product package is open or damaged when received, do not use this device.

Wilson-Cook devices should be stored in a dry location, away from temperature extremes.

CONTRAINDICATIONS

Contraindications include those specific to ERCP.

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

The wire guide diameter and the inner lumen of the wire guided device must be compatible. The Color Connection® provides instant recognition of compatible wire guides and devices through color coding on the device and the package.

The coordination of endoscope accessory channel size with compatible devices is essential in obtaining optimal results during a procedure. All Stricture Measuring Catheters are 5.0 FR and require a minimum channel size of 2.0 mm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CAUTIONS

A thorough understanding of the technical principles, clinical applications and risks associated with ERCP is necessary before using this device. The Stricture Measuring Catheter should only be used by, or under the supervision of, physicians thoroughly trained in ERCP.

Wilson-Cook wire guides are recommended for use with this device.

Injection of contrast during ERCP should be monitored fluoroscopically. Overfilling of the pancreatic duct may cause pancreatitis.

INSTRUCTIONS FOR USE

1. Upon removal of the device from the package, uncoil the catheter and visually inspect with particular attention to kinks, bends, or breaks. If an abnormality is detected that would prohibit proper working condition, do not use. Please notify Wilson-Cook for return authorization.
Note: If the product package has been opened inadvertently and the device not used, the device may be resterilized ***one time only.*** Refer to the table at the end of these instructions for the recommended ETO sterilization cycle parameters. Package the device for sterilization following AAMI recommended practices.

2. Gently advance the stylet completely into the Stricture Measuring Catheter. Lock the stylet cap into the catheter fitting.

3. Introduce the catheter into the endoscope and advance, in short increments, until the device is endoscopically visualized exiting the scope.

4. Following cannulation, contrast may be injected to fluoroscopically confirm the position of the device by attaching a syringe to the side port of the catheter fitting. The tip of the Stricture Measuring Catheter has radiopaque bands at 1 cm intervals in order to measure the stricture and determine the appropriate stent size.

5. A wire guide may be placed in the duct to maintain position and facilitate the exchange of compatible wire guided devices. Remove the stylet from the catheter and advance a compatible wire guide prior to removing the catheter from the endoscope.
Note: Before each introduction of a wire guide into a device, wet the wire guide in a sterile water or saline bath. A contrast filled catheter may make the wire guide difficult to advance. Flush the contrast from the catheter with sterile water or saline before each introduction of the wire guide, observing the necessary cautions if the device is positioned in the pancreatic duct.

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ORDERING INFORMATION

	CATHETER		STYLET	WIRE GUIDE*	
Order Number	French Size	Length	Length	Diameter	Color Connection
SMC-1	5.0	200 cm	100 cm	.035 inch	Purple

*Wire Guide sold separately.

ETO CYCLE PARAMETERS

PARAMETER	SET POINT
Prevacuum Pressure	2.0 psia (-25.9" Hg Vac)
Relative Humidity	60% RH
Humidity Dwell	20 minutes
Chamber Temperature	54.4 °C (130 °F)
Exposure Pressure	To Be Determined[1]
Exposure Dwell	2 hours
ETO Concentration	600 mg/L
Post Vacuums	3
Post Vacuum Pressure	2.0 psia (-25.9" Hg Vac)
Air Wash[2]	5 minutes
Aeration Temperature	54.4 °C (130 °F)
Aeration Dwell	12 hours
Air Changes During Aeration	90 per hour

[1] To be calculated by the Institution to achieve an ETO concentration of 600 mg/L.
[2] Repetitive vacuums from ambient pressure to 13.7 psia over 5 minutes.

NOTE: ETO sterilizer chamber loading should not exceed 11 products per cubic foot of chamber space or exceed the usable chamber space. If any damage to a product is noted prior to sterilizing, it should be taken out of service immediately.

NOTE: AAMI stands for Association for the Advancement of Medical Instrumentation.

PROCEDURE NOTES

Wilson-Cook is a registered trademark of Wilson-Cook Medical Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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INTENDED USE

The Glo-Tip ERCP Catheter is used for endoscopic cannulation of the ductal system. This single lumen catheter allows injection of contrast or provides wire guide access to the desired duct. This device is supplied sterile and is intended for single use only.

NOTES

To ensure these instructions are current, please contact Customer Service if the purchase date of this product has exceeded two years.

Do not use this device for any purpose other than the stated intended use.

Inventory rotation of sterile products is essential. Verify the expiration date on the package label prior to using the product. If the expiration date has lapsed, do not use or resterilize the device.

If the product package is open or damaged when received, do not use or resterilize this device.

Wilson-Cook devices should be stored in a dry place, away from temperature extremes.

CONTRAINDICATIONS

Contraindications include those specific to ERCP.

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

The wire guide diameter and the inner lumen of the wire guided device must be compatible. The Color Connection® provides instant recognition of compatible wire guides and devices through color coding on the device and the package.

The coordination of endoscope accessory channel size with compatible devices is essential in obtaining optimal results during a procedure. The diameter of the GT-5-4-3 is 5 FR and requires a minimum channel of 2 mm. All other Glo-Tip catheters are 5.5 FR and require a minimum channel of 2.8 mm.

CAUTIONS

A thorough understanding of the technical principles, clinical applications and risks associated with ERCP is necessary before using this device. The Glo-Tip ERCP Catheter should only be used by, or under the supervision of, physicians thoroughly trained in ERCP.

Wilson-Cook wire guides are recommended for use with this device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Injection of contrast during ERCP should be monitored fluoroscopically. Overfilling of the pancreatic duct may cause pancreatitis.

INSTRUCTIONS FOR USE

1. Upon removal of the device from the package, uncoil the catheter and visually inspect with particular attention to kinks, bends, or breaks. If an abnormality is detected which would prohibit proper working condition, do not use. Please notify Wilson-Cook for return authorization.

2. Gently advance the stylet into the Glo-Tip catheter. Lock the stylet cap into the catheter fitting. *(See fig. 1)*

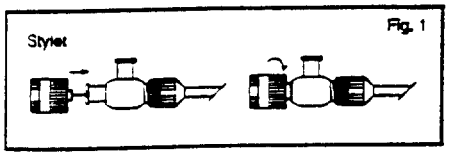

Fig. 1

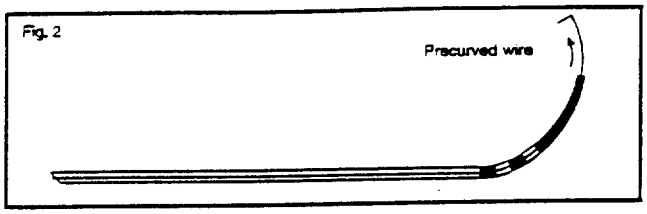

Fig. 2

Note: When using the GT-5-4-3, remove and discard the precurved wire from the tip of the catheter prior to introducing the device into the endoscope. *(See fig. 2)*

3. Introduce the catheter into the endoscope and advance, in short increments, until the device is endoscopically visualized exiting the scope.

4. Following cannulation, contrast may be injected to fluoroscopically confirm the position of the device by attaching a syringe to the side port of the catheter fitting. The Glo-Tip catheter has a radiopaque tip to assist with fluoroscopic visualization.

5. A wire guide may be placed in the duct to maintain position and facilitate the exchange of compatible wire guided devices. Remove the stylet from the catheter and advance a compatible wire guide prior to removing the catheter from the endoscope. **Note:** Before each introduction of a wire guide into a device, wet the wire guide in a sterile water or saline bath. A contrast filled catheter may make the wire guide difficult to advance. Flush the contrast from the catheter with sterile water or saline before each introduction of the wire guide, observing the necessary cautions if the device is positioned in the pancreatic duct.

Note: The Glo-Tip Ultra Taper and Glo-Tip 5-4-3 feature the Mark V System™ which is an endoscopically visualized measurement system with graduated markings at 5 cm increments on the cannulating portion of the device. The Mark V System may be utilized to determine the required stent length and to verify cannulation depth. *(See fig. 3)*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

510(k) Number (if known): _____

Device Name: Wilson-Cook Stricture Measuring Catheter

Indications For Use: The Wilson-Cook Stricture Measuring Catheter is used to measure biliary and pancreatic strictures to determine stent size. This catheter allows injection of contrast and provides wire guide access to the desired duct. 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)

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

(Optional Format 1-2-96)

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