

K973205

**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

NOV 24 1997

**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<sup>-6</sup>.

**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

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 RGP CATHETER (K853964)
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.



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,

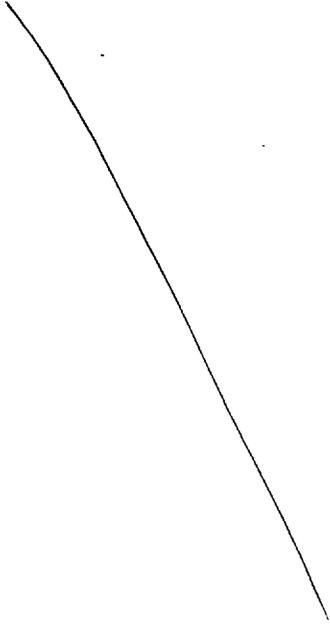
Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): \_\_\_\_\_

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Robert D. Anthony*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K973205

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

OR

Over-The-Counter Use \_\_\_\_\_