

JUN 25 2004

ATTACHMENT E: 510(k) Summary

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

CONTACT/SUBMITTER: Marge Walls-Walker
Regulatory Affairs Specialist
[336] -744-0157 Ex.290

DATE OF SUBMISSION: March 25, 2004

DEVICE: Biliary Dilation Balloon

Trade Name: Wilson-Cook Biliary Dilation Balloon
Common Name: Biliary Dilation Balloon
Classification: Dilator, Esophageal, Class II 78 KNQ
21 CFR § 876.5365

PREDICATE DEVICES: Wilson-Cook Quantum T.T.C.Dilation Balloon (k935094)
Microvasive RX Biliary Balloon Dilation Catheter (k001338)

INTENDED USE: Wilson-Cook's Biliary Dilation Balloon is intended to dilate strictures in the biliary tree. This device is supplied sterile and intended for single use

DEVICE DESCRIPTION: The proposed Wilson-Cook Biliary Dilation Balloon is a triple lumen catheter with a balloon mounted on the distal tip. The three lumens allow one lumen for wire guide access and two lumens for inflation/deflation of the balloon when placed through the accessory channel of an endoscope. The balloon is inflatable with water to nominal pressures to exert force on biliary strictures resulting in stricture dilation. It is offered in a variety of diameters to accommodate a range of biliary strictures

COMPARISON OF CHARACTERISTICS: We believe the proposed device to be substantially equivalent to the named predicates in terms of Intended Use, Indications for Use, performance characteristics tested, balloon diameter and length available and biocompatibility.

PERFORMANCE DATA: Non-Clinical Testing was performed on characteristics of the balloon with respect to *The FDA Guidance for Urological Balloons* and additional tests as needed to verify safety and performance.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2004

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

Re: K040800

Trade/Device Name: Wilson-Cook Biliary Dilation Balloon
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: March 25, 2004
Received: March 29, 2004

Dear Ms. Walls-Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

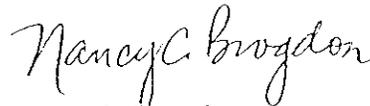
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

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

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



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

Enclosure

510(k) Number (if known): K 040800

Device Name: Wilson-Cook Biliary Dilation Balloon

indications for Use:

The Wilson-Cook Biliary Dilation Balloon is intended to dilate strictures of the biliary tree. This device is supplied sterile and intended for single use only.

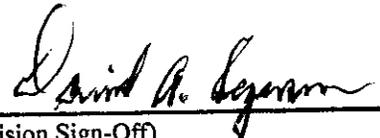
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE-IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only
(Per 21 CFR § 801.109)

OR

Over-the-Counter



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K040800