JUL - 2 2004

ATTACHMENT F: 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:

April 8, 2004

DEVICE:

Zilver Biliary Stent System-USW

Trade Name:
Common Name:
Classification:

Wilson-Cook Zilver Biliary Stent System-USW
Expandable Metal Biliary Stent
Catheter, Biliary, Class II, GU/ 78 FGE
21 CFR § 876.5010

PREDICATE DEVICES:

Wilson-Cook Zilver Biliary Stent (k020788)

INTENDED USE:

Wilson-Cook's Zilver Biliary Stent System-USW is intended for palliation of malignant neoplasms in the biliary tree. This device is supplied sterile and intended for single use.

DEVICE DESCRIPTION:

The proposed Wilson-Cook Zilver Biliary Stent System-USW is a catheter within a catheter configuration. The pre-loaded (SEMS) Zilver Stent is held between the inner and outer catheter by natural expansion force at the distal tip. The inner catheter allows for wire guide access when placed through the accessory channel of an endoscope. The stent is self-expanding to nominal pressures to exert force on malignant neoplasms in the biliary tree resulting in dilation. It is offered in a variety of diameters/lengths to accommodate a range of biliary tumors.

COMPARISON OF CHARACTERISITICS:

We believe the proposed device to be substantially equivalent to the named predicate in terms of Intended Use, Indications for Use, performance characteristics tested, stent diameter and length available and biocompatibility.

PERFORMANCE DATA:

Non-Clinical Testing was performed on characteristics of the stent with respect to *The FDA Guidance for the Content of PreMarket Notifications for Metal Expandable Biliary Stents* and additional tests as needed to verify safety and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2004

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

Re: K040930
Trade/Device Name: Wilson Cook Zilver Biliary Stent System USW – Device Modification
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: June 3, 2004
Received: June 4, 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

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.

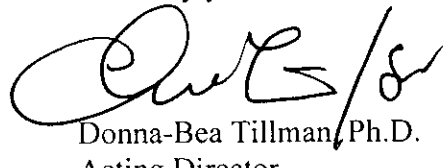
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K040930

Device Name: Wilson-Cook Zilver Biliary Stent System USW – Device Modification

FDA's Statement of the Indications For Use for device:

The Wilson-Cook Zilver Biliary Stent System USE is indicated for the palliation of malignant neoplasms in the biliary tree.

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

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040930