2/12/99

K990130
pg 1 of 2

RE: SPECIAL 510 (K) : DEVICE MODIFICATION FOR THE WILSON-COOK PANCREATIC STENT

J. **510(k) Summary of Safety & Effectiveness**

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

Device Description: The Modified Wilson-Cook Pancreatic Stent is a sterile, disposable device, used to drain obstructed pancreatic ducts.
Trade Name: Wilson-Cook Pancreatic Wedge Stent
Common/Usual Name: Pancreatic Stent
Classification Name/Code: Catheter, Biliary, GU/78 FGE
Classification: FDA has classified similar devices as Class II as per 21 CFR § 876.5010. This device falls within the purview of the theGastroenterology and Urology Devices Panel.
Establishment Registration Number: 1037905

Sterility: Validated EO cycle in accordance with AAMI Standard 11135 using an SAL of 10^{-6}.

Performance Standards: No performance standards applicable to Biliary Catheters have been established by the Food and Drug Administration.

Intended Use: Used to drain obstructed pancreatic ducts.
Predicate Devices:

Predicate Device	Manufacturer	Document Control Number
Wilson-Cook Pancreatic Stent	Wilson-Cook Medical Inc.	K900923

Substantial Equivalence:
The Modified Wilson-Cook Pancreatic Stent is substantially equivalent to the referenced predicate devices in that it is similar with respect to technological characteristics and intended use.

J. **510(k) Summary of Safety & Effectiveness (continued)**

Characteristic	Predicate Wilson-Cook Pancreatic Stent (K900529)	Modified Wilson-Cook Pancreatic Stent (Subject of Special 510(k))
Intended Use	Drain obstructed pancreatic ducts.	Drain obstructed pancreatic ducts.
Stent	Polyethylene	Polycarbonate based Polyurethane
Introducer Components	Polyethylene	Polytetrafluoroethylene
Sterility	Sterile, Disposable	Sterile, Disposable
Wire Guide	Accepts .035" wire guide	Accepts .035" wire guide

Characteristic	Predicate Wilson-Cook Pancreatic Stent (K900529)	Modified Wilson-Cook Pancreatic Stent (Subject of Special 510(k))
Stent Configuration	Pigtail ends for retention	Tapered ends for retention
Dimensions	Stent French Sizes: 5,7,9, 10 Stent Length: 1-15 cm	Stent French Sizes: 6, 8, 10 Stent Length: 4-24 cm
Introducer Components	Pushing Catheter Wire Guide	Pushing Catheter Guiding Catheter Wire Guide (Available separately)

Biocompatibility: Reasonable assurance of biocompatibility for the patient contacting materials has been established through an extensive history of use in similar patient contacting medical devices and as applicable biocompatibility test results.

Design Control/Risk Analysis/Design Verification:
Design Control, risk analysis and design verification activities for the subject of this 510(k) have been conducted in accordance with all applicable internal procedures. The design control process employed is inclusive of the elements as stipulated by 21CFR § 820.30, as applicable to the project. The risk analysis performed identified the risks relative to the performance requirements, as specified by our internal procedure for Risk Analysis. The failure mode, effect of failure, severity, potential cause, rate of occurrence, design control element/production controls to eliminate, the potential to detect and our recommended actions were also documented. During Design Verification, dimensional and functional testing to ensure the performance and design integrity of this product line was conducted. All results obtained during our Design Verification met our predetermined acceptance criteria for this product line.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 1999

Ms. Paula Joyce
QA/RA Manager
Wilson Cook® Medical Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K990130
Wilson-Cook® Pancreatic Wedge Stent
Dated: January 13, 1999
Received: January 14, 1999
Regulatory Class: II
21 CFR 876.5010/Procode: 78 FGE

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 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. 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting 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): **K990130**

Device Name: **Wilson-Cook Pancreatic Wedge Stent**

Indications For Use:

Used to drain obstructed pancreatic ducts

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990130