

3/25/99

K990145
242

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK BIPOLAR PROBE

I. 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 Bipolar Probe is comprised of a mono or dual plug, flush port, catheter shaft and probe. The dual or single plug is located at the proximal end of the catheter shaft and is used for connection to the appropriate bipolar generator. The flush port is also located at the proximal end of the catheter and is used as necessary for irrigation. The distal tip of the device is the probe component used for hemostasis.

Trade Name: Wilson-Cook Bipolar Probe

Common/Usual Name: Bipolar Probe

Classification Name/Code: Unit, Electrosurgical, Endoscopic (with or without accessories)/78 KNS

Classification: FDA has classified similar devices as Class II, as per 21 CFR § 876.4300. 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.

Intended Use: Used in conjunction with single or dual plug bipolar electrosurgical generators to endoscopically provide hemostasis throughout the gastrointestinal tract.

Predicate Device:

PREDICATE DEVICE	MANUFACTURER	DOCUMENT CONTROL NUMBER
Dobhoff Bipolar Hemostatic Probe	Biosearch Medical Products, Inc.	K912129

Substantial Equivalence:

The Wilson-Cook Bipolar Probe is substantially equivalent to the referenced predicate device with respect to design, materials of construction and intended use.

K990145
142

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK BIPOLAR PROBE

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

DEVICE CHARACTERISTIC	Wilson-Cook Bipolar Probe [Subject of 510(K)]	Biosearch Hydromer[®] grafted Bipolar Hemostatic Probe (K912129)
Intended Use	Used in conjunction with single or dual plug bipolar electro-surgical generators to endoscopically provide hemostasis throughout the gastrointestinal tract.	The probe is designed to function as a conventional electro-coagulation device when supplied with current from a standard bipolar electro-surgical generator. The device is intended to be passed through an endoscope's working channel to provide hemostasis throughout the GI tract.
Sterility	Sterile, Disposable	Non-Sterile, Disposable

Testing: Biocompatibility has been established for the patient contacting materials through a history of use in the Biosearch Bipolar Probe. This product line has been subjected to Design Verification. During Design Verification, visual, dimensional and functional testing to ensure the performance, design integrity for this product line was conducted. All results obtained during our Design Verification met our predetermined acceptance criteria for this product line.



MAR 25 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Ms. Paula Joyce
QA/RA Manager
Wilson-Cook® Medical, Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105Re: K990145
Wilson-Cook® Bipolar Probe
Dated: January 15, 1999
Received: January 19, 1999
Regulatory Class: II
21 CFR 876.4300/Procode: 78 KNS

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

