



OCT 31 1995

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Wilson-Cook Medical, Inc.
c/o Neal E. Fearnot, Ph.D., E.E.
President, Med Institute, Inc.
P.O. Box 2402
West Lafayette, Indiana 47906

Re: K934356
Trade Name: Endoscopic Ultrasound Needle
Dated: September 20 and October 7, 1994
Received: September 21 and October 11, 1994
Regulatory Class: II
Product Code: FCG
21 CFR 876.1075

Dear Dr. Fearnot:

We have reviewed the information referenced above which was submitted in response to our August 31, 1994, letter, concerning the labeling for your GI Aspiration Needle. We acknowledge the certification in your letter dated September 20, 1994, that no reference to claims of intended use for biopsy outside the GI tract will be made in the labeling of this device. We also note that the name of your device has been changed from "GI Aspiration Needle" to "GI Endoscopic Ultrasound Needle" and we acknowledge the name change.

Based on the additional information submitted, we have determined the device is substantially equivalent 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.

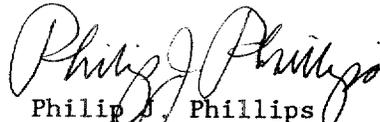
This determination hereby supersedes and amends our substantially equivalence order dated January 7, 1994, and clears for marketing the Endoscopic Ultrasound Needle with only an intended use "to sample targeted submucosal gastrointestinal lesions through the accessory channel of an ultrasound endoscope." The amended order no longer allows marketing of your product for paraesophageal locations including the mediastinum, as well as the liver, pancreas and retroperitoneum,.

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR

Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 immediately will allow you to begin marketing your device (K934356) originally cleared for marketing January 7, 1994, with the modifications described in the information you have provided in your letters dated September 20, and October 7, 1994, and received September 21, and October 11, 1994. An 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, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Philip J. Phillips
Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health

I. 510(K) SUMMARY

Submitted By:

Neal Fearnot
MED Institute, Incorporated
1400 Cumberland
West Lafayette, Indiana 47906
(317) 463-7537
September 3, 1993

Device:

Trade Name: Wilson-Cook GI Aspiration Needle
Common/Usual Name: Biopsy Aspiration Needle, Suction Biopsy
Instrument
Proposed Classification: Gastroenterology Biopsy Instrument

Predicate Devices:

The Wilson-Cook GI Aspiration Needle is a gastroenterology biopsy instrument which is similar to predicate Wilson-Cook Medical biopsy aspiration needles.

Device Description:

The Wilson-Cook GI Aspiration Needle is used to perform gastrointestinal (GI) tract biopsy. The device is supplied sterile and is intended for one-time use. The construction materials comprising the Wilson-Cook GI Aspiration Needle are biocompatible, having an established history of use in medical products.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program. The device will undergo packaging and sterilization procedures similar to devices currently manufactured and marketed by Wilson-Cook Medical. This device is similar with respect to indications for use and design to predicate devices in terms of section 510(k) substantial equivalency.

