K984157

RE: SPECIAL 510 (K) : DEVICE MODIFICATION FOR THE WILSON-COOK LUNG BIOPSY NEEDLE

DEC 8 1998

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 Lung Biopsy Needle is a sterile, disposable device, used for submucosal aspiration biopsy of the bronchial tree through the accessory channel of a bronchoscope. It consists of a 22 gauge needle, 100 cm outer catheter and handle mechanism. The handle mechanism is used to extend and retract the needle with the proximal portion inclusive of the aspiration port.

Trade Name: Wilson-Cook Lung Biopsy Needle
Common/Usual Name: Aspiration Needle
Classification Name/Code: Bronchoscope Accessory 77 ~~KTI~~ EOQ
Classification: FDA has classified similar devices as Class II as per 21 CFR § 874.4680. This device falls within the purview of the Ear, Nose and Throat Device 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 Bronchoscope Accessories have been established by the Food and Drug Administration.

Intended Use: Used for submucosal aspiration biopsy of the bronchial tree.

Predicate Devices:

Predicate Device	Manufacturer	Document Control Number
Wilson-Cook Lung Biopsy Needle	Wilson-Cook Medical Inc.	K8977050A
Transbronchial Aspiration Needle	Wang/Mill-Rose	K914181

Substantial Equivalence:
The modified Lung Biopsy Needle 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 Lung Biopsy Needle (K897050A)	Predicate Wang/Mill-Rose Transbronchial Aspiration Needle (K914181)	Modified Wilson-Cook Lung Biopsy Needle [Subject of "Special" 510(k)]
Intended Use	Biopsy of lung tissue.	Aspiration biopsy of the bronchial tree.	Submucosal aspiration biopsy of the bronchial tree.
Outer Catheter	Polytetrafluoroethylene with metal hub at distal tip.	Polytetrafluoroethylene with metal hub at distal tip.	Polyetheretherketone (PEEK) with metal hub at distal tip.
Needle	22 GA stainless steel needle affixed to an inner catheter	22 GA Needle	22 GA stainless steel needle.
Maximum Needle Extension	13mm	13mm	13mm
Outer Catheter Length	100cm	140 cm	100cm
Sterility	Sterile, Disposable	Sterile, Disposable	Sterile, Disposable

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 to eliminate, the potential to detect and our recommended actions were also documented. During Design Verification, visual, 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

DEC 8 1998

Wilson-Cook Medical, Inc.
C/O Paula Joyce
QA/RA Manager
4900 Bethania Station Rd.
Winston-Salem, NC 27105

Re: K984157
Wilson-Cook Lung Biopsy Needle
Dated: November 13, 1998
Received: November 19, 1998
Regulatory class: II
21 CFR 874.4680/Procode: 77 EOQ

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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Re: Special 510(k): Device Modifcation for the Wilson-Cook Lung Biopsy Needle.

510(k) Number (if known): k984157

Device Name: Wilson-Cook Lung Biopsy Needle

Indications For Use:

Used for submucosal aspiration biopsy of the bronchial tree.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984157

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)