MAY 1 1998

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K980046

Applicant Information:

Date Prepared:	January 5, 1998
Name:	Broncus Technologies, Inc.
Address:	1400N. Shoreline Boulevard Mountain View, CA 94043
Contact Person:	Glendon E. French
Phone Number:	(650) 428-1600
Fax Number:	(650) 428-1542

Device Information:

Classification	Class II
Trade Name:	Bronchial Catheter System
Classification Name:	Bronchoscope and Accessories 21 CFR 874.4680

Equivalent Devices:

The subject device is substantially equivalent in intended use and/or method of operation to a combination of the following predicate devices:

1. Olympus — Disposable Balloon Catheters
2. Boston Scientific — Microvasive Gold Probe Direct
3. Valleylab, Inc. — Force 2 Electrosurgical Generator

Intended Use:
The Bronchial Catheter System is intended to be used for foreign body removal and bronchial hemostasis.

510(k) Summary of Safety and Effectiveness, continued

Comparison To Predicate Devices:

The Broncus Technologies Bronchial Catheter System is equivalent in intended use and operational characteristics to the Olympus Disposable Balloon Catheters and the Microvasive Gold Probe when used with the Valleylab Force 2 RF Generator.

Non-Clinical Test Results:

Performance
The performance of the Bronchial Balloon Catheter was evaluated *in vitro* and shown to be equivalent to the performance of the predicate devices.

Biocompatibility
The materials used in the Bronchial Balloon Catheter have proven biocompatibility.

Summary:

Based on the intended use, product, performance and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 1998

Glendon E. French
President and CEO
Bronchus Technologies, Inc.
1400 N. Shoreline Blvd.
Building A. Suite 8
Mountain View, California 94043

Re: K980046
Bronchial Catheter System
Dated: April 10, 1998
Received: April 13, 1998
Regulatory class: II
21 CFR 874.4680/Procode: 77 EOQ
21 CFR 878.4400/Procode: 79 GEI

Dear Mr. French:

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

Indications for Use

510(k) Number (if known): K980046

Device Name: Bronchial Catheter System

Indications for Use:

The Bronchial Catheter System is intended for foreign body removal and bronchial hemostasis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980046

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

(Optional Format 1-2-96)