JAN 2 8 2000

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: K993900

Applicant Information:

Date Prepared:	January 17, 2000
Name:	Broncus Technologies, Inc.
Address:	1400 N. Shoreline Boulevard Building A, Suite 8 Mountain View, CA 94043
Contact Person:	John D'Angelo
Phone Number:	(650) 428-1600 ext. 312
Fax Number:	(650) 428-1542

Device Information:

Classification	Class II
Trade Name:	Broncus™ Coagulation Electrode 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 the following predicate devices:

Broncus Technologies, Inc.	Broncus™ Bronchial Catheter System
Olympus America Inc.	Coagulation Electrode
Valleylab, Inc.	Force 2 Electrosurgical Generator

Description:

The *Broncus* Coagulation Electrode System consists of a catheter, a RF generator, and a commercially available patient return electrode. The RF generator produces RF power in a monopolar mode. The catheter delivers RF energy to the desired target site and relays temperature and other feedback to the RF generator. The patient return electrode is used to complete the return path for the electrical current.

Intended Use:

The *Broncus* Coagulation Electrode System is intended for coagulation or hemostasis in the tracheobronchial tree.

510(k) Summary of Safety and Effectiveness, continued

Comparison to Predicate Devices:

The *Broncus* Coagulation Electrode System is substantially equivalent in intended use and/or method of operation to the named predicate devices.

Non-Clinical Test Results:

Performance
The Coagulation Electrode System has undergone and passed functional and electrical testing designed to assess the performance of the catheter and the RF generator.

Biocompatibility
The materials used in the Coagulation Electrode have proven biocompatibility.

Summary of Substantial Equivalence:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2000

Mr. John D'Angelo
President and CEO
Broncus Technologies, Inc.
1400 N. Shoreline Blvd.
Building A, Suite 8
Mountain View, CA 94043

Re: K993900
Trade Name: Coagulation Electrode, Model 2000; Radiofrequency Generator
Regulatory Class: Class II
Product Code: 874.4680, 77EOQ and 878.4400, 79GEI
Dated: November 15, 1999
Received: November 16, 1999

Dear Mr. D'Angelo:

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/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K993900

Device Name: Broncus™ Coagulation Electrode System

Indications for Use:

The Broncus™ Coagulation Electrode System is intended for coagulation or hemostasis in the tracheobronchial tree.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Karen A. Baker

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K993900