K024165

510(k) Summary

JAN 1 0 2003

Trade Name: **Dual-Lumen Catheter**

Sponsor: Bistech, Inc.
10A Roessler Road
Woburn, MA 01801
Registration # not yet assigned

Device Generic Name: Multi-Lumen Catheter

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Predicate Devices:

Product Name	510(k) #	Manufacturer
Aspiration Needle Set	Unknown	Olympus
Stifcor Transbronchial Aspiration Needle	K963252	Boston Scientific – Microvasive
Combicath Double Plugged Telescoping Catheter	K974632	Plastimed

Product Description:
The proposed device consists of a two-lumen catheter with proximal bifurcation and luer hubs. The device will be supplied with a removable stylette in one of the lumens that is intended to provide support and prevent kinking as the catheter is inserted through the working channel of a bronchoscope.

Indications for Use:
The Dual-Lumen Catheter is intended for use with a bronchoscope to deliver fluids to or withdraw fluids from the lung.

Safety and Performance:
This submission is an Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Bistech, Inc. has provided information to demonstrate conformity with the following FDA-recognized consensus standard:

- ISO 10555-1;1999 (Amendment 1) *Sterile, Single Use Intravascular Catheters*

Conclusion:
Based on its indications for use, technological characteristics, and comparison to predicate devices, the Dual-Lumen Catheter has been shown to be safe and effective for its intended use.

Substantial Equivalence: Bistech Dual-Lumen Catheter

Feature \ Product	Bistech Dual-Lumen Catheter (current submission)	Olympus Aspiration Needle Set (510(k) # unknown)	BSC-Microvasive Stifcor Transbronchial Aspiration Needle (K963252)	Plastimed Combicath Double Plugged Telescoping Catheter (K974632)
Outer Diameter	1.7 mm	1.85 mm	1.8 mm	2.6 mm
Working Length	100 cm	105 cm	150 cm	Unknown
# of Lumens	Two	One	One	Two
Design	Dual-lumen catheter	Reusable metallic coil sheath; single-use disposable needle	Extendable coaxial needle within single lumen catheter	Dual-lumen catheter with distal polyethylene glycol plug
Packaging	Tyvek/Plastic Pouch	Tyvek/Plastic Pouch	Tyvek/Plastic Pouch	Tyvek/Plastic Pouch
Sterile/ Non-Sterile	Sterile	Non-sterile (reprocessable) sheath; Sterile needle	Sterile	Sterile
Single Use/ Reusable	Single Use	Reusable sheath; Single use needle	Single Use	Single Use
Anatomical Sites of Use	Tracheobronchial tree	Tracheobronchial tree	Tracheobronchial tree	Tracheobronchial tree
Indications for Use	To deliver fluids into or withdraw fluids from the lung	To aspirate tissue and cells from the respiratory organs	Bronchial aspiration	Mini-bronchoalveolar lavage; collection of bronchoalveolar samples

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 0 2003

Bistech, Inc.
c/o Pamela Papineau, RAC
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, MA 01432

Re: K024165
Trade/Device Name: Bistech Dual-Lumen Catherer
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: December 5, 2002
Received: December 17, 2002

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

A. Ralph Rosenthal

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

Enclosure

510(k) Number (if known): K024165

Device Name: Dual-Lumen Catheter

Indications for Use:

For use with a bronchoscope to deliver fluids to or withdraw fluids from the lung.

(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)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K024165