K091250

MAY 22 2009

Cardinal Health
1430 Waukegan Road
McGaw Park, Illinois 60085-6787
847.578.6610
FAX: 847.785.2506

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Ventilator Acquired Pneumonia

Sponsor:	Cardinal Health 1430 Waukegan Road MPKB-3B McGaw Park, IL 60085
Regulatory Affairs: Contact	Sharon Nichols
Telephone:	(847) 578-6610
Date Summary Prepared:	March 2009
Common Name:	Diagnostic Catheter System
Classification Name:	Bronchoscope, flexible or rigid and accessories
Classification:	Class II per 21CFR §874.4680
Predicate Devices:	Primary – Combicath, K974642, Plastimed Secondary - Balcath, K923487, Balllard
Description:	The Diagnostic Catheter System is a device that consists of an improved non-bronchoscopic Bronchoalveolar Lavage (BAL) catheter to be used for the blind retrieval of lower respiratory tract secretions (also know as mini-BAL).

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Intended Use:	The Diagnostic Catheter System is intended for use as a sampling device by performing mini-bronchoalveolar lavage in adult patients undergoing mechanical ventilation in order to obtain lower respiratory tract samples for laboratory testing and diagnosis.
Summary of Technological Characteristics:	The proposed device and the predicate device are composed of the same or similar design, materials and the manufacturing characteristics. Summary of testing: All materials used in the fabrication of the Diagnostic Catheter System were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". These materials also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.
Non-Clinical Testing:	Performance testing demonstrated that the proposed device is substantially equivalent to the currently marketed devices with regard to functional characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2009

Cardinal Health, Inc.
c/o Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, Illinois 60062
Attn: Ned Devine

Re: K091250
Trade/Device Name: Diagnostic Catheter System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: II
Product Code: EOQ
Dated: May 14, 2009
Received: May 19, 2009

Dear Mr. Devine:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K091250

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Indication for Use

510(k) Number (if known):	Unknown at this time
Device Name:	Diagnostic Catheter System
Indications For Use:	The Diagnostic Catheter System is intended for use as a sampling device by performing mini-bronchoalveolar lavage in adult patients undergoing mechanical ventilation in order to obtain lower respiratory tract samples for laboratory testing and diagnosis.

Prescription Use _X_ or Over-The Counter Use _____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K091250