DEC 1 5 2011

510(K) Summary K 112562

Date Summary was Prepared:	November 22, 2011
510(k) Submitter:	David M. Lee, J.D. Associate Director of Regulatory Affairs Kimberly-Clark Health Care 1400 Holcomb Bridge Road Roswell, GA 30076 Ph: 770.587.7167 FAX: 920.225.4784 Email: David.Lee@kcc.com
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Device Trade Name:	Kimberly-Clark* KimVent* BAL Cath* Bronchial Aspirate Sampling Catheter (Product Code 143)
Device Common names	BAL Cath*
Device Product Codes and Classification Names:	OYI, Class I Catheters, suction, tracheobronchial (21 CFR 868.6810)
Predicate Devices	The Kimberly-Clark* KimVent* BAL Cath* Bronchial Aspirate Sampling Catheter is substantially equivalent to the predicate device, BAL Cath* (K923487).
Device Description:	Sterile, single use, catheter kit for performing non-bronchoscopic Brochoalveolar Lavage (BAL) in adult patients undergoing mechanical ventilation. (also known as mini-BAL)

Intended Use:	The Kimberly-Clark* KimVent* BAL Cath* Bronchial Aspirate Sampling Catheter is used in the diagnosis of diffuse lung disease by allowing collection of bronchoalveolar lavage (BAL) specimens from deep within the lung. The use of a bronchoscope is not necessary. This catheter is used in adult intubated patients.
Technological Characteristics and Substantial Equivalence:	The performance testing of the Kimberly-Clark* KimVent* BAL Cath* Bronchial Aspirate Sampling Catheter demonstrates that it is substantially equivalent to the predicate device, BAL Cath* (K923487) in intended use, design, packaging, manufacturing, biocompatibility, and performance. The Kimberly-Clark* KimVent* BAL Cath* Bronchial Aspirate Sampling Catheter incorporates a smaller catheter diameter. This difference in diameter raises no new issues of safety and efficacy.
Summary of Testing:	The Kimberly-Clark* KimVent* BAL Cath* Bronchial Aspirate Sampling Catheter has been tested for physical performance by bench testing demonstrating substancial equivalence to the predicate device and conformance to the applicable sections of the following standards: ISO 594-2:1998, ISO 10993-5:2009, ISO 10993-7:2008, ISO 10993-10:2010, ISO 11135-1:2007, and ISO 5356-1:2004. All results of testing met acceptance criteria.

*Registered Trademark or Trademark of Kimberly-Clark Worldwide, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 15 2011

Mr. David M. Lee, J.D.
Associate Director of Regulatory Affairs
Kimberly-Clark Healthcare
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Re: K112562
Trade/Device Name: Kimberly-Clark* KimVent *BAL Cath* Bronchial Aspirate Sampling Catheter
Regulation Number: 21 CFR 868.6810
Regulation Name: Tracheobronchial Suction Catheter
Regulatory Class: I
Product Code: OYI
Dated: August 31, 2011
Received: September 26, 2011

Dear Mr. Lee:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Kimberly-Clark* KimVent* BAL Cath* Bronchial Aspirate Sampling Catheter

Indications for Use:

The Kimberly-Clark* KimVent* BAL Cath* Bronchial Aspirate Sampling Catheter is used in the diagnosis of diffuse lung disease by allowing collection of bronchoalveolar lavage (BAL) specimens from deep within the lung. The use of a bronchoscope is not necessary. This catheter is used in adult intubated patients.

Prescription Use ___x___
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) L Schuster
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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