MAY 1 1 2012

510(K) SUMMARY (REVISED)

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

APPLICANT	Kimberly-Clark* 1400 Holcomb Bridge Road Roswell, GA 30076
OFFICIAL CORRESPONDENT	Marcia Johnson Technical Leader, Regulatory Affairs Tel: 770.587.8566 Fax: 920.380.6351 email: marcia.johnson@kcc.com
TRADE NAME:	Kimberly-Clark* KimVent* Microcuff* Endotracheal Tubes for Adults
CLASSIFICATION NAME:	Tracheal tubes
DEVICE CLASSIFICATION AND PRODUCT CODE	Class II per 21 CFR §868.5730 Product Code - BTR

SUBSTANTIAL EQUIVALENCE:

The modified Kimberly-Clark* KimVent* Microcuff* Endotracheal Tubes for Adults (sizes 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 10.0 mm) are substantially equivalent to the Adult Cuffed ET Tubes; Standard cleared under K050803. Both the Kimberly-Clark* KimVent* Microcuff* Endotracheal Tubes for Adults and the predicate device have the same intended use and same fundamental scientific technology.

Bench testing has demonstrated that the modified Kimberly-Clark* KimVent* Microcuff* Endotracheal Tubes for Adults performs the same function as the predicate device, and that any minor differences between the modified device and the predicate device would have positive impact to safety or efficacy.

DESCRIPTION OF THE DEVICE:

The Kimberly-Clark* KimVent* Microcuff* Endotracheal Tubes for Adults are available in sizes 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 10.0 mm. They are available as Magill and made with an ultra-thin polyurethane cuff, referred to as the MicroCuff*.

INDICATIONS FOR USE:

KIMVENT* MICROCUFF* Endotracheal Tubes for Adults are indicated for airway management by nasal or oral intubation of the trachea in adult patients.

TECHNILOGICAL CHARACTERISTICS

KIMVENT* MICROCUFF* Endotracheal Tubes for Adults have the same fundamental technological characteristics as the predicate device, the Adult Cuffed ET Tubes; Standard cleared under K050803. Both are polyvinylchloride (PVC) endotracheal tubes designed with a polyurethane high volume low pressure cuff (referred to as the Microcuff*) and have an attached pilot balloon with a one-way Luer-slip adapter.

CLAIMS

- The Microcuff* tube with its cylindrical shaped polyurethane cuff provides a superior tracheal seal for a wider range of trachea sizes and cuff sealing pressures compared to leading PVC cuffed tubes.
- KimVent* Microcuff* Endotracheal Tubes reduce microaspiration by at least 95% when compared to the Covidien Hi-Lo PVC cuffed tube and at least 93% when compared to the Covidien TaperGuard tube with a tapered PVC cuff.
- At 10 cm H2O cuff pressure, the Microcuff* tube demonstrated 96% less microaspiration compared to the Covidien TaperGuard tube.

In benchtop testing, the use of the KimVent Microcuff Endotracheal tubes, with its polyurethane cuff, has also demonstrated superior tracheal seal and less microaspiration when compared to similar endotracheal tubes utilizing a polyvinyl chloride cuff.

PERFORMANCE DATA:

Functional test results met acceptance criteria and demonstrate that the device is safe and effective for use in humans.

CONCLUSION:

Based on the performance testing, it can be concluded that the modified Kimberly-Clark* KimVent* Microcuff* Endotracheal Tubes for Adults are equivalent to the predicate, Adult Cuffed and Uncuffed ET Tubes (K050803).

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

Ms. Marcia Johnson
Technical Leader, Regulatory Affairs
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, Georgia 30076

MAY 11 2012

Re: K113333
Trade/Device Name: Kimberly-Clark* KimVent Microcuff* Endotracheal Tubes for Adults
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal tube
Regulatory Class: II
Product Code: BTR
Dated: May 9, 2012
Received: May 10, 2012

Dear Ms. Johnson:

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, 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* Microcuff* Endotracheal Tubes for Adults.

Indications For Use:

KIMVENT* MICROCUFF* Endotracheal Tubes for Adults are indicated for airway management by nasal or oral intubation of the trachea in adult patients.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

L Schultz

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

510(k) Number: 113333