K080821

APR 22 2008

510(K) SUMMARY

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	Sherry Saurini Associate Director, Regulatory Affairs Tel: 770.587.8502 Fax: 920.969.3455 email: sherry.saurini@kcc.com
TRADE NAME:	KIMBERLY-CLARK* MICROCUFF Pediatric ET Tubes
CLASSIFICATION NAME:	Tracheal tubes
DEVICE CLASSIFICATION AND PRODUCT CODE	Class II per 21 CFR §878.5730 Product Code - BTR

SUBSTANTIAL EQUIVALENCE:

The modified Kimberly-Clark* MICROCUFF Pediatric ET Tubes (3.0, 3.5, 4.0, 4.5mm) are substantially equivalent to the Pediatric Cuffed and Uncuffed ET Tubes; Standard cleared under K050803. Both the Kimberly-Clark* MICROCUFF Pediatric ET Tubes and the predicate device have the same intended use and basic scientific technology.

Bench testing has demonstrated that the modified Kimberly-Clark* MICROCUFF Pediatric ET Tubes 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.

510(K) SUMMARY

DESCRIPTION OF THE DEVICE:

The Kimberly-Clark* MICROCUFF Pediatric ET Tubes are available in sizes 3.0 to 4.5 in increments of 0.5 mm. They are available as Magill and pre-formed, made with an ultra thin polyurethane cuff, referred to as the MicroCuff.

INDICATIONS FOR USE:

The Kimberly-Clark* MICROCUFF Pediatric Endotracheal Tubes are designed for oral / nasal intubation and are indicated for airway management

PERFORMANCE DATA:

Biocompatibility, sterilization and functional test results met acceptance criteria and demonstrate that the device is safe and effective for use in humans. A sterilization summary can be found in Attachment D. Biocompatibility summaries can be found in Attachment E.

CONCLUSION:

Based on the performance testing, it can be concluded that the modified Kimberly-Clark* MICROCUFF Pediatric ET Tubes (3.0, 3.5, 4.0, 4.5mm) are equivalent to the predicate, Pediatric Cuffed and Uncuffed ET Tubes (K050803).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2008

Ms. Sherry Saurini
Associate Director, Regulatory Affairs
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Re: K080821
Trade/Device Name: Kimberly-Clark* MICROCUFF Pediatric ET Tubes
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: March 21, 2008
Received: March 25, 2008

Dear Ms. Saurini:

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 (240) 276-0115. 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 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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* MICROCUFF Pediatric ET Tubes

Indications For Use:

The Kimberly-Clark* MICROCUFF Pediatric Endotracheal Tubes are designed for oral / nasal intubation and are indicated for airway management.

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)

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

510(k) Number: K080821