Kimberly-Clark Corporation

Section 3 – 510(K) Summary K120985

DEC 19 2012

Date Summary was Prepared:	December 19, 2012
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Device Trade Name:	KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes
Device Common names:	Endotracheal Tubes
Device Product Codes and Classification Names:	BTR Class II Endotracheal Tubes (21 CFR 868.5730)
Predicate Devices:	The Kimberly-Clark* KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes are substantially equivalent to the predicate device, TaperGuard Evac™ Endotrachael Tubes (K090352).
Device Description:	KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes are available in adult sizes 7.0, 7.5, 8.0, 8.5, and 9.0mm with a Murphy Eye. They include a separate lumen with a dorsal opening above the cuff to provide access to the subglottic space. The subglottic space is accessed via a normally open suction valve that includes a one-way port for rinsing the subglottic space with sterile saline (0.9% Sodium Chloride solution) or administering an air bolus to assist in maintaining a patent suction lumen patency. These devices are sold as disposable, sterile, single-use, devices.

Intended Use:

KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes are indicated for airway management by oral intubation of the trachea and for removal of secretions that accumulate in the subglottic space.

Technological Characteristics

Both the Kimberly-Clark* KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes and the predicate TaperGuard Evac™ Endotracheal Tubes have the same basic fundamental technological characteristics. Both are polyvinylchloride tubes with inflatable cuffs and include a suction lumen. The Kimberly-Clark* KimVent* Microcuff* Subglottic Suctioning Endotracheal Tube incorporates a barrel-shaped polyurethane inflatable cuff while the predicate TaperGuard Evac™ Endotracheal Tubes contain a tapered PVC cuff. The Kimberly-Clark* KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes incorporate a suction valve with integrated rinse port to aid in removing secretions that accumulate in the subglottic space while the predicate TaperGuard Evac™ Endotracheal Tubes contain a single port for access to the subglottic space. Below is a comparison table that summarizes the technological characteristics of the subject and predicate tubes:

	Predicate Device – TaperGuard Evac™ Endotrachael Tubes (K090352)	**Subject Device – Kimberly-Clark* KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes**
Materials		
Endotracheal Tube	Polyvinylchloride Tube (PVC) with Radiopaque line	PVC tube w/Barium Sulphate Radiopaque line
Pilot Balloon Assembly	Plasticol or PVC Pilot Balloon One-way valve (Bespak valve) = PVC, Plastic Acetal copolymer, Nitrile Rubber, stainless steel Inflation Tail = PVC	PVC Pilot Balloon One-way valve (Bespak Check Valve) = PVC, Nitizile/Acetal/ stainless steel Inflation Tube/Tail = PVC
Inflatable Pressure Cuff	PVC with a tapered-shape	Polyurethane with a barrel-shape
Suction System	PVC	PVC Tube with Acrylonitrile Butadiene Styrene (ABS) valve
Vent Connector	PVC	Polypropylene

	Predicate Device – TaperGuard Evac™ Endotrachael Tubes (K090352)	Subject Device – Kimberly-Clark* KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes
Ink	Medical Grade Ink	All inks were confirmed to be non-cytotoxic, non-irritating and non-sensitizing through appropriate ISO 10993 testing.
Adhesives	Solvents used for assembly: Cyclohexanone, Balloon Glue, Cyclohexanone/Scanning compound No. 5.	UV-Cure Adhesives, Cyanoacrylate Adhesive
Sizes	6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 (mm)	7.0, 7.5, 8.0, 8.5, 9.0 (mm)
Shelf-life	5-year	Launch with 2-year, will extend to 5-year using established protocols

Summary of Testing:

Bench-top performance testing was conducted to confirm suctioning efficiency and additional bench-top testing was conducted to assure conformance to the following standards.

- ISO 5356-1:2004, Anesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets:
- ISO 5361:1999, Anesthetic and respiratory equipment - Tracheal tubes and connectors.

Biocompatibility testing was conducted to assure conformance to the following standards:

- ANSI/AAMI/ISO 10993-3: 2003 Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity,
- ANSI/AAMI/ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity
- ANSI/AAMI/ISO 10993-6, 2007 Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects After Implantation
- ANSI/AAMI/ISO 10993-10: 2010: Biological evaluation of medical devices - Part 10:Tests for Irritation and Skin Sensitization

The product is EO sterilized and validated according to the following standards:

- ANSI/AAMI/ISO 10993-7:2008, Biological evaluation of medical devices, Part 7: Ethylene oxide sterilization residuals, Section 4.3.3 Prolonged Exposure Devices.
- ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.
- ANSI/AAMI/ISO 11607-1 2006 - Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.

Results of all testing met acceptance criteria.

Conclusion:

The Kimberly-Clark* KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes are substantially equivalent to the predicate device, TaperGuard Evac™ Endotracheal Tubes (K090352), in intended use, design, performance, principles of operation, and both are intended for single use. Test results confirm that the device is as safe, as effective, and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 19, 2012

Ms. Marcia Johnson, RAC
Technical Leader, Regulatory Affairs
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
ROSWELL GA 30076

Re: K120985
Trade/Device Name: KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: November 26, 2012
Received: November 28, 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,

Kwame O. Ulmer

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

Enclosure

Section 2 - Indications for Use

510(k) Number (if known): K120985

Device Name: KimVent® Microcuff® Subglottic Suctioning Endotracheal Tubes

Indications for Use:

KimVent® Microcuff® Subglottic Suctioning Endotracheal Tubes are indicated for airway management by oral intubation of the trachea and for removal of secretions that accumulate in the subglottic space.

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)

Lester W. Schultheis Jr
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K120985