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Section 3 - 510K Summary

Date Summary was Prepared: June 04, 2012

510(k) Submitter: David M. Lee, JD
Associate Director, 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

Primary Contact for this 510(k) Submission: David Lee
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

Device Trade Name: Kimberly-Clark* MIC-KEY* SF Low Profile Gastrostomy Tube and Accessories

Device Common names: Gastrointestinal FeedingTubes

Device Product Codes and Classification Names: KNT Class II
21 CFR 876.5980
Gastrointestinal tube and accessories

Predicate Devices: The Kimberly-Clark* MIC-KEY Low Profile Gastrostomy Tube and accessories cleared under K043114 and K993138.

Device Description: Low profile Gastrostomy feeding tube and accessories to facilitate nutrition, medication delivery, and gastric decompression for single patient use.

Intended Use: The Kimberly-Clark* MIC-KEY* SF Low Profile Gastrostomy Tube and Accessories are indicated for use in patients who require long term feeding, are unable to tolerate oral feeding, who are at low risk for aspiration, require gastric decompression

and/or medication delivered directly into the stomach through a secured (initial placement) or formed (replacement) stoma.

Kimberly-Clark* MIC-KEY* SF Continuous Feed Extension Set is indicated for use with the MIC-KEY* SF Low Profile Gastrostomy Tube to facilitate nutrition, medication delivery, and gastric decompression.

Kimberly-Clark* MIC-KEY* SF Bolus Feed Extension Set is indicated for use with the MIC-KEY* SF Low Profile Gastrostomy Tube to facilitate nutrition, medication delivery, and gastric decompression.

Kimberly-Clark* MIC-KEY* SF Patient Starter Kit is indicated to provide necessary components to begin enteral feeding after placement of the Kimberly-Clark* MIC-KEY* SF Gastrostomy Tube.

Kimberly-Clark* MIC-KEY* SF Over-the-Wire Stoma Measuring Device is indicated for measuring the length of a stoma prior to placement of a low profile feeding tube.

**Technological
Characteristics:**

The Kimberly-Clark* MIC-KEY* SF Low Profile Gastrostomy Tube external feeding head, feeding catheter, and disc-shaped retention balloon are manufactured with polyurethane. The feeding catheter is inserted into the stomach through a secured or formed stoma and is held in place with a retention balloon that is filled with sterile or distilled water. The device is provided with feeding catheter outer diameters that range from 10Fr to 24Fr, and with feeding tube lengths that range from 0.8cm to 6.0cm to fit different stoma diameters and lengths, respectively. The device incorporates a balloon fill indicator to alert the user when the balloon is not optimally inflated and incorporates an extension set connector that snaps with an audible double click that helps confirm that the connection of the extension set is secure. In addition, the feeding port includes a one-way dome valve that does not require a closure cap/strap.

The Kimberly-Clark* MIC-KEY* SF Bolus Feed Extension Set and Kimberly-Clark* MIC-KEY* SF Continuous Feed Extension Set engage to the feeding port using a snap-in connector and are made from DEHP-free materials. The feed valve and extension set ports have been designed to help prevent misconnections with Luer style connectors in alignment with ISO 80369-1 requirements.

Summary of Testing:

The Kimberly-Clark* MIC-KEY* SF Over-the-Wire Stoma Measuring Device consists of a head, catheter, retention balloon, that are composed of polyurethane.

The Kimberly-Clark* MIC-KEY* SF Low Profile Gastrostomy Tubes and Accessories have been tested for conformance to the applicable sections of the following standards:

- ISO 10993-1: 2009 Biological Evaluation of Medical Devices-Part 1: Evaluation and testing within a risk management process
- ISO 10993-3: 2009 Biological Evaluation of Medical Devices-Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
- ISO 10993-5 2009 Biological Evaluation of Medical Devices-Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6: 2007 Biological Evaluation of Medical Devices-Part 6: Test for Local Effects After Implantation
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ISO 10993-10-2010 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and delayed-type Hypersensitivity
- ISO 10993-11: 2006 Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity
- ISO 10993-12: 2007 Biological Evaluation of Medical Devices-Part 12: Sample Preparation and Reference Materials
- ANSI/AAMI/ISO 11607-1 (2006) - Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11135-7:2007 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 ID54:1996/(R)2012 - Enteral feeding set adapters and connectors
- ASTM F640-07 – Standard Test Methods for Determining Radiopacity for Medical Use

All results of testing met acceptance criteria.

Conclusion:

Based upon the results of the performance testing conducted, the Kimberly-Clark* **MIC-KEY* SF Low Profile Gastrostomy Tube and Accessories** are substantially equivalent to the predicate devices cleared under K043114 and K993138 in intended use,

design, biocompatibility, performance, and principles of operation.



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

June 26, 2013

Kimberly-Clark Corporation
% Mr. Ned Devine
Sr. Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

Re: K122653
Trade/Device Name: Kimberly-Clark* MIC-KEY* SF Low Profile
Gastrostomy Tube and Accessories
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: June 11, 2013
Received: June 12, 2013

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 contact 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>. 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,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Section 2 - Indications for Use

510(k) Number (if known): K122653

Device Name: **Kimberly-Clark* MIC-KEY* SF Low Profile Gastrostomy Tube and Accessories**

Indications for Use:

The Kimberly-Clark* MIC-KEY* SF Low Profile Gastrostomy Tube and Accessories are indicated for use in patients who require long term feeding, are unable to tolerate oral feeding, who are at low risk for aspiration, require gastric decompression and/or medication delivered directly into the stomach through a secured (initial placement) or formed (replacement) stoma.

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Kimberly-Clark* MIC-KEY* SF Over-the-Wire Stoma Measuring Device is indicated for measuring the length of a stoma prior to placement of a low profile feeding tube.

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)

Herbert P. Lerner -S

K122653

Section 2 – Indications for Use

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