K093312
1 of 2

510(k) Summary

Preparation Date: November 6, 2009

Applicant: Kimberly Clark Corporation
1400 Holcomb Bridge Road
Roswell, GA 30097

DEC - 8 2009

Contact Person: Lester F. Padilla
Tel. No.: 678-352-6766
Fax. No. 920-382-6682

Trade/Proprietary Name(s): Device 1: Kimberly-Clark Gastrointestinal Anchor Set with Saf-T-Pexy* T-Fasteners

Device 2: Kimberly-Clark Enteral Access Dilation System

Common Name(s): Device 1: Gastropexy Device
Device 2: Stoma Dilator

Classification Name: Gastrointestinal tube and accessories
(21 CFR Part 876.5980, Product Code KGC)

Legally Marketed Device to Which Substantial Equivalence is Claimed:
1. Kimberly-Clark Introducer Kits (K080253)

Device Description(s):
1. The Kimberly-Clark Gastrointestinal Anchor Set with Saf-T-Pexy™ T-Fasteners consists of an internal retention T-Bar and an external suture-lock retention bolster connected by a length of resorbable suture. The T-Bar end is loaded onto the slot of a safety needle.

2. The Kimberly-Clark Enteral Access Dilation System is a stoma dilator with a peel-away sheath composed of a series of HDPE (high density polyethylene) telescoping dilator sleeves. It is available in 5 terminal sizes from 16FR up to 24FR (every even size).

Intended Use(s):
1. Gastrointestinal Anchor Set with Saf-T-Pexy* T-Fasteners:
The Kimberly-Clark Gastrointestinal Anchor Set with Saf-T-Pexy™ T-Fasteners is intended to affix the stomach to the anterior abdominal wall facilitating primary placement of the Kimberly-Clark MIC and MIC-Key brand Enteral Feeding Tubes. It is recommended that these T-Fasteners be used only with the Kimberly-Clark MIC and MIC-KEY brand Enteral Feeding Tubes.

2. Enteral Access Dilation System
The Kimberly-Clark Enteral Access Dilation System is intended to facilitate stoma tract dilation prior to placement of the Kimberly-Clark MIC and MIC-Key brand Enteral Feeding Tubes. It is recommended that these dilator be used only with the Kimberly-Clark MIC and MIC-KEY brand Enteral Feeding Tubes

Summary of Technologies:
The technological characteristics (design, materials of construction, sizes) of the Gastrointestinal Anchor Set with Saf-T-Pexy* T-Fasteners and the Enteral Access Dilation System are identical to the predicate device.

Clinical and Non-Clinical Testing:
No Clinical or Non-clinical laboratory testing were not required to determine substantial equivalence since the subject devices are identical to the device components of the predicate device.

K093312
2 of 2

Conclusion:
The Kimberly-Clark Gastrointestinal Anchor Set with Saf-T-Pexy™ T-Fasteners and the Kimberly-Clark Enteral Access Dilation System are substantially equivalent to the predicate devices, the Kimberly-Clark Introducer Kits (K080253) since the subject devices are identical to the components of the predicate device and there are no changes to the technological characteristics or intended uses of the devices.

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

Kimberly-Clark Corporation
c/o Mr. Casey Conry
Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
MELVILLE NY 11747

DEC - 8 2009

Re: K093312
Trade/Device Name: Kimberly-Clark Gastrointestinal Anchor Set with Saf-T-Pexy™ T-Fasteners; and, Kimberly-Clark Enteral Access Dilation System
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KGC
Dated: November 19, 2009
Received: November 23, 2009

Dear Mr. Conry:

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 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093312

Device Name: Kimberly-Clark Gastrointestinal Anchor Set with Saf-T-Pexy™ T-Fasteners

Indications for Use:

The Kimberly-Clark Gastrointestinal Anchor Set with Saf-T-Pexy™ T-Fasteners is intended to affix the stomach to the anterior abdominal wall facilitating primary placement of the Kimberly-Clark MIC and MIC-Key brand Enteral Feeding Tubes. It is recommended that these T-Fasteners be used only with the Kimberly-Clark MIC and MIC-KEY brand Enteral Feeding Tubes.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K093312

262

Indications for Use

510(k) Number (if known): K093312

Device Name: Kimberly-Clark Enteral Access Dilation System

Indications for Use:

The Kimberly-Clark Enteral Acccess Dilation System is intended to facilitate stoma tract dilation prior to placement of the Kimberly-Clark MIC and MIC-Key brand Enteral Feeding Tubes.

It is recommended that these dilator be used only with the Kimberly-Clark MIC and MIC-KEY brand Enteral Feeding Tubes

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093312