K080328

510(k) Summary

1. Submitter:

MPS Acacia
785 Challenger Street
Brea, CA 92821
Tel: 714-257-0470
Fax: 714-257-0513

MAY 14 2008

2. Contact:

Fergie F. Ferguson, Quality Systems Manager
MPS Acacia

3. Date prepared: February 6, 2008

4. Device trade name: MPS Acacia Enteral Feeding Tube

   Common name: Feeding Tube

5. Predicate device: Argyle Indwell Polyurethane Feeding Tube
   510(k) number: K820442
   Marketed by: Kendall
   15 Hampshire Street
   Mansfield, MA 02048

   Predicate device: Argyle PVC Feeding Tube
   510(k) number: K820441
   Marketed by: Kendall
   15 Hampshire Street
   Mansfield, MA 02048

6. Description:

   The MPS Acacia Enteral Feeding Tube is a polyurethane or polyvinyl chloride (PVC) tube of various French sizes and lengths. A rigid female oral connector is attached to the proximal end of the Enteral Feeding Tube and accepts all male oral connectors such as those found on oral syringes.

7. Intended Use:

   7.1 The MPS Acacia Enteral Feeding Tube is intended to be placed into the stomach, nasogastrically or orogastrically, for the introduction of fluids and/or oral medication.

   7.2 The Enteral Feeding Tube is disposable and single use only.

   7.3 Not intended for intravascular or intravenous use.

8. Technological comparison to predicate device:

   MPS Acacia's Enteral Feeding Tube utilizes the Kendall's Feeding tube with MPS Acacia's rigid female oral connector attached in the place of Kendall's soft boot female connector. MPS Acacia's oral female connector can only accept an oral male connector such as those found on oral syringes.

   There are no other technological differences between the proposed MPS Acacia Enteral Feeding Tube and the predicate devices marketed by Kendall.

9. Non-clinical test summary:

The Kendall Polyurethane and PVC Feeding Tubes are legally marketed devices in the United States. The attachment of MPS Acacia's oral female connector does not require additional clinical testing since no changes in the common clinical use or intended use of the device is being made.

10. Conclusion:

The MPS Acacia Enteral Feeding Tube utilizes the Kendall Feeding Tube and MPS Acacia's rigid female oral connector. All standard male oral connectors, such as those found on oral syringes, can connect with the rigid female oral connector.

MPS Acacia Enteral Feeding Tube is substantially equivalent to the predicate devices marketed by Kendall since there are no technological or intended use differences between the two devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2008

Mr. Fergie F. Ferguson
Quality Systems Manager
MPS Acacia
785 Challenger St.
BREA CA 92821

Re: K080328
Trade/Device Name: MPS Acacia Enteral Feeding Tube
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: March 25, 2008
Received: March 26, 2008

Dear Mr. Ferguson:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
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): K080328

Device Name: MPS Acacia Enteral Feeding Tube

Indications for Use:

1. The MPS Acacia Enteral Feeding Tube is intended to be placed into the stomach, nasogastrically or orogastrically, for the introduction of fluids and/or oral medication.
2. The Enteral Feeding Tube is disposable and single use only.
3. Not intended for intravascular or intravenous use.

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)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080328