JUN 19 2014

abbvie AbbVie PEG K133087
Traditional 510(k) Notification
510(k) Summary

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Sponsor: AbbVie Inc.
1 N. Waukegan Road
North Chicago, IL 60064

Contact: Katherine Wortley, Ph.D.
Director Regulatory Affairs
AbbVie Inc.
Telephone: (847) 938-7707
Fax: (847) 775-4997
Email: Katherine.wortley@abbvie.com

Date Prepared: September 30, 2013

Device:

Trade Name: AbbVie™ PEG

Common Name: Gastrostomy Tube

Classification Name: Tubes, Gastrointestinal and Accessories
21 CFR 876.5980, Product Code KNT, Class II

Predicate Device: EndoVive™ Initial Placement PEG Kit, K030855

Device Description:

The AbbVie™ PEG is a percutaneous endoscopic gastrostomy (PEG or gastric) tube, either 15 FR or 20 FR and 35 cm in length. The kit includes the following: AbbVie PEG Tube (polyurethane), Reel of Thread with double thread and Introducer Device, Puncture

Cannula with safety (air) valve, Disposable Scalpel, Silicone external Fixation Plate (radio-opaque) with integrated Tube Clip, and Tube Clamp.

Device Intended Use:

The AbbVie PEG is intended to provide long-term enteral access for administration of medication to the small intestine when used in conjunction with the AbbVie J, intestinal tube. As needed, enteral nutrition may be administered directly to the stomach in parallel with medication delivery to the intestine.

Comparison of Product Characteristics:

The AbbVie PEG is substantially equivalent to the currently marketed device, EndoVive™ Initial Placement PEG Kit (K030855). Both devices are percutaneous endoscopic gastrostomy tubes. The tubes have the same fundamental structure and function. Both devices are single use, sterile and provide an opening into the stomach for feeding and insertion of an intestinal tube. Differences include tube material and indications for use (the AbbVie PEG is indicated for the administration of medication and enteral feeding, the EndoVive Initial Placement PEG Kit for enteral feeding).

Non-Clinical Performance Data:

The performance characteristics of the AbbVie PEG have been verified based on the conformance to applicable industry standards. The material composition of the AbbVie PEG shows acceptable performance across all protocols tested for biocompatibility per ISO 10993-1:2009 *Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process*. The AbbVie PEG was assessed for conformance to standard EN 1615:2000 *Enteral feeding catheters and enteral giving sets for single use and their connectors – Design and testing*. An assessment of the AbbVie PEG has been completed and shown to be acceptable per ISO 80369-1:2010 *Small-bore Connectors for Liquids and Gases in Healthcare Applications- Part 1: General requirements*. Food contact testing was conducted on the AbbVie PEG and demonstrated that the materials that constitute the AbbVie PEG are acceptable for food

contact use. The study was conducted as described in 21 CFR 177.2600 *Indirect Food Additives: Polymers, Rubber articles intended for repeated use* per the extractable limits.

Clinical Performance Data:

No clinical evaluations were performed or relied upon for the determination of substantial equivalence.

Conclusion:

The information provided within this pre-market notification demonstrates that the AbbVie PEG has no differences that would affect the safety or effectiveness of the device as compared to the predicate device, EndoVive Initial Placement PEG Kit. The differences between the two devices do not raise new issues of safety or effectiveness. The AbbVie PEG is substantially equivalent to 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

June 19, 2014

AbbVie, Inc.
Katherine Wortley, Ph.D., RAC
Director Regulatory Affairs
1 N. Waukegan Road
North Chicago, IL 60064

Re: K133087
Trade/Device Name: AbbVie™ PEG
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: May 15, 2014
Received: May 16, 2014

Dear Katherine Wortley,

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

Indications for Use

510(k) Number (if known): K133087

Device Name: AbbVie™ PEG

Indications for Use:

The AbbVie PEG is intended to provide long-term enteral access for administration of medication to the small intestine when used in conjunction with the AbbVie J, intestinal tube. As needed, enteral nutrition may be administered directly to the stomach in parallel with medication delivery to the intestine.

Prescription Use _X____ AND/OR Over-The-Counter Use ____

(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)

Herbert P. Lerner -S
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