K061021
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ConMed™
ENDOSCOPIC TECHNOLOGIES

APR 28 2006

## 510(K) Summary of Safety and Effectiveness

1. Sponsor Name: ConMed Endoscopic Technologies, Inc.
129 Concord Rd.
Billerica, MA 01821
Telephone: 978-964-4251
Contact Individual: Beth Zis
Vice President of Regulatory Affairs

2. Device Name:
Trade Name: EnTake™ PEG Standard and Safety System
Classification Name: Gastrointestinal Tubes and Accessories

3. Identification of Predicate or Legally Marketed Device:

Kimberly-Clark MIC™ PEG Standard and Safety Kit, cleared under K924065.
Boston Scientific EndoVive™ PEG Standard and Safety Kit, cleared under K031538.

4. Device Description
The EnTake PEG Standard and Safety System contains a gastrostomy feeding tube, external retention bolster, two-port feeding adapter, feeding tube clamp packaged sterile in a kit containing procedural aides. The EnTake PEG System consist of both standard and safety kits in both push and pull versions. Standard kits contain the components that are typically used in the procedure. Safety kits contain alternative safety versions of the scalpel, the needle introducer and the 5 cc syringe.

The EnTake PEG System will be offered in a variety of sizes and variations that allow for installation via guidewire (push) or pull wire, placement in a new gastrostomy.

5. Intended Use
For percutaneous placement of a long-term initial-placement feeding and/or decompression device.

6. Comparison of Technological Characteristics
The EnTake ™ PEG Standard and Safety System is substantially equivalent to the predicate devices both in intended use, technological characteristics, and materials.

7. Performance Testing
Biocompatibility and bench testing have been performed to demonstrate equivalence of the device to its predicates. All testing passed the predetermined performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2006

ConMed Corporation
c/o Intertek Testing Services NA, Inc.
Mr. Daniel W. Lehtonen
2307 East Aurora Road
Unit B7
TWINSBURG OH 44087

Re: K061021
Trade Name: EnTake Standard and Safety PEG System
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tubes and Accessories
Regulatory Class: II
Product Code: KNT
Dated: April 12, 2006
Received: April 13, 2006

Dear Mr. Lehtonen:

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 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 (the Act). You may, therefore, market the device, subject to the general controls provisions of 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 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/tray. 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); 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.

In addition, we have determined that your device kit contains povidone-iodine swabs, povidone-iodine ointment, and lidocaine which are subject to regulation as drugs.

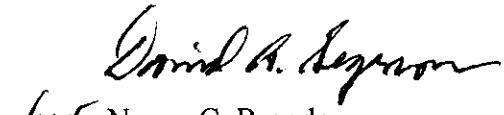
Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). 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) 443-6597, or at its Internet address http://www.fda.gov/cdrh.dsma/dsmamain.html.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

K061021

C. INDICATIONS FOR USE K061021

510(k) Number (if known):

Device Name: EnTake ™ PEG Standard and Safety System

Indications For Use:

For percutaneous placement of a long-term initial-placement feeding and/or decompression device.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061021