K083684
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510(k) Summary of Safety and Effectiveness

FEB - 5 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter Name:	Manufacturing and Research, Inc.
Submitter Address :	4700 S. Overland Dr., Tucson, AZ 85714
Contact Person:	Suzanne Dew
Phone Number:	520-882-7794 x109
Fax Number:	520-882-6849
Date Prepared:	November, 2008
Device Trade Name:	EndoVive™ Standard Replacement GastrostomyTube
Device Common Name:	Tube, Gastro-enterostomy
Classification Name:	Tube, Gastro-enterostomy, product code KNT
Predicate device:	Microvasive Balloon Gastrostomy Tube Kit, K962375 EndoVive™ Low Profile Button Replacement Gastrostomy Tube, K014297
Reason for submission:	Not previously marketed in the USA

Device Description and Materials:
The EndoVive™ Standard Replacement GastrostomyTube is constructed primarily of silicone. The device consists of a tri-port funnel which is overmolded onto a previously extruded bi-lumen shaft. A retention bolster is molded separately and placed over the shaft. At the proximal end, a silicone balloon is bonded to the shaft using a silicone RTV. The tip of the shaft is filled with a radiopaque barium RTV. In use, the balloon end of the catheter is inserted into an established stoma, the balloon inflated with 3 mL saline, and the bolster slide down to the skin to secure the device in place. There are two versions of the bolster, a straight version and a right angle

Intended Use:
The EndoVive™ Standard Replacement Gastrostomy Tube is indicated in adult and pediatric populations for use in percutaneous placement of an Enteral feeding tube for feeding and/or administration of medication in conjunction with an established GI stoma tract. Typical uses include the replacement of existing gastrostomy feeding tubes. In addition, the 20F tube is also used for the replacement of initial placement jejunostromy feeding tubes. The replacement tube may also be used for decompression.
Note: Only the 20F tube is indicated for jejunal replacement.

Substantial Equivalence/ Device - Technological Characteristics and Comparison to Predicate Device(s):
The EndoVive™ Standard Replacement Gastrostomy Tube is substantially equivalent to the Microvasive Balloon Gastrostomy Tube Kit, K962375 and EndoVive™ Low Profile Button Replacement Gastrostomy Tube, K014297

Among the information and data presented in the 510(k) submission to support the substantial equivalency of the EndoVive™ Standard Replacement Gastrostomy Tube to the specified predicate devices are: 1) device description, 2) indications for use, 3) bench test results, 4) materials, and 5) labeling. In particular, the bench testing demonstrated there was no difference in the performance, safety, or effectiveness between the EndoVive™ Standard Replacement Gastrostomy Tube and the specified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2009

MRI Medical, Inc.
c/o Mr. Mark Job
Reviewer
Regulatory Technology Services LLC
1395 25th Street, N.W.
BUFFALO MN 55313

Re: K083684
Trade/Device Name: EndoVive™ Standard Replacement Gastrostomy Tube
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: January 16, 2009
Received: January 21, 2009

Dear Mr. Job:

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 os 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (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 Manufactures, 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.suppot/index.html.

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: K083684

***Device Name*: EndoVive™ Standard Replacement Gastrostomy Tube**

***Indications For Use*:**

The EndoVive™ Standard Replacement Gastrostomy Tube is indicated in adult and pediatric populations for use in percutaneous placement of an Enteral feeding tube for feeding and/or administration of medication in conjunction with an established GI stoma tract. Typical uses include the replacement of existing gastrostomy feeding tubes. In addition, the 20F tube is also used for the replacement of initial placement jejunostromy feeding tubes. The replacement tube may also be used for decompression.
Note: Only the 20F tube is indicated for jejunal replacement.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K083684