K971401
1 of 1

JAN 22 1998

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k): Regulatory & Marketing Services, Inc. (RMS)
40178 U.S. 19 North
Tarpon Springs, FL 34689

Phone: 813-942-3908
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Contact Person: Ed Ransom or Pat Lamb

Date of Summary: May 23, 1997

Trade Name: Radius Low Profile Gastrostomy Tube Kit

Classification Name: Tube, Gastro-Intenstinal

Predicate Device: Bard Button Replacement Gastrostomy Device

Device Description/ Comparison:

The Low Profile Gastrostomy Tube Kit is a collection of medical devices that are assembled for the convenience of the health care professional for the purpose of creating a percutaneous gastrostomy through which an enteral feeding tube is placed. The Kit contains items that are commonly used in this type of procedure and which otherwise would be procured through the facility's central supply system.

The units are packaged in a kit form with related feeding components and is ethylene oxide sterilized. It is packaged in a preformed plastic tray, and is sealed with a 1073B tyvek lid containing a description of the kit components. This packaging is similar to the predicate unit and is a system commonly used in the medical device industry.

Intended Use: The device is a low profile replacement gastrostomy tube kit designed for percutaneous insertion through an established stoma tract.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 1998

Radius International, Inc.
c/o Edward H. Ransom
Consultant
Regulatory and Marketing Services
P. O. Box 1108
Elfers, Florida 34680

Re: K971901
Radius Low Profile Gastrostomy Tube Kit
Regulatory Class: II
Product Code: 78 KNT
Dated: October 24, 1997
Received: October 27, 1997

Dear Mr. Ransom:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Robert R Nathan/

for Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971901

Device Name:

Indications For Use:

The device is indicated for percutaneous placement of a low-profile long term gastrostomy feeding and decompression device through an established stoma.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Rathbun

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971901

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)