K972102
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JAN 23 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
Fax: 813-942-3828

Contact Person: Ed Ransom or Pat Lamb

Date of Summary: May 30, 1997

Trade Name: Radius Push Over the Guide Wire Percutaneous Endoscopic Gastrostomy Kit

Classification Name: Tube, Gastro-Intenstinal

Predicate Device: Bard Guidewire System Peg Tray

Device Description/ Comparison: The device is described as a Percutaneous Endoscopic Gastrostomy tube. The device may be life supporting in that it can be the primary source of nutrition for the patient. The indications, complications and contra-indications are identical to those of the predicate Bard device. The actual insertion and placement techniques are also identical. The bolster and connector systems perform the same functions as those performed by the Bard unit. The dilator portion of the over-the-guidewire peg is composed of the same medical grade polyethylene material that is used by Bard and is identical in design. The internal bolster system is comparable to the Bard system in both retention and removal characteristics.

Intended Use: The kit is a collection of medical devices that are assembled for the purpose of creating a percutaneous gastrostomy through which an enteral feeding tube is placed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 1998

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

Re: K972102
Radius Push PEG 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 (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. 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 (Premarket Approval) 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 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.

In addition, we have determined that your device kit contains Lidocaine, Povidone-iodine swab, and Povidone - iodine ointment, 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 this 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 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 and additionally 809 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 Tallung

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): K972102

Device Name: Radius Push Over the Guide Wire Percutaneous Endoscopic Gastrostomy Kit

Indications For Use:

The device is indicated for percutaneous placement of a long term initial placement feeding and/or decompression gastrostomy device.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P Rathbun

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972102

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

(Optional Format 1-2-96)