9.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K023846

General Provisions	Trade Name: MR Compatible Model 90 Electrosurgical Probe Common/Classification Name: Electrosurgical cutting and coagulation accessory
Name of Predicate	RITA Medical Systems Inc. - Model 90 Electrosurgical Probe Radiotherapeutics Corp. – MR Compatible LeVeen Needle Electrode
Classification	Class II
Performance Standards	Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.
Intended Use	The MR Compatible Model 90 Electrosurgical Probe is designed to supply energy (generated by the RITA Medical Systems' Electrosurgical Generator) for use in electrosurgery and is designed for the following: • Incorporation of multiple needles on each probe minimizing the number of invasive accesses necessary to achieve desired lesions. • Provide a minimally invasive laparoscopic, percutaneous, or intraoperative access to the targeted tissue. • Deliver radiofrequency energy in a controlled fashion to create coagulative necrotic lesions. • Incorporate thermocouples for temperature feedback. • Provide for local delivery of fluid.
Device Description	This RITA® MR Compatible Model 90 device is available in 15 cm and 25 cm lengths for a variety of medical applications. The secondary electrodes deploy out from the trocar tip. The RITA MR Compatible Model 90 device consists of the following components: • *primary electrode*: hypodermic tubing with a portion exposed as an electrode • *secondary electrodes*: extendible flexible hypodermic tubing at the distal end of probe • *trocar insulation*: shrink tubing • *handle*: polymer materials with markings to indicate the amount of electrode array deployment from the trocar • *RF pathway*: connection through a Lemo connector built into the handle • *fluid infusion*: delivery through Luer port at side of the handle • *temperature sensors*: five temperature sensors at the periphery of the array • *depth indicators*: Incremental 1-cm marks denote needle penetration depth.
Performance Data	The MR Compatible Model 90 devices were subjected to a battery of electrical, mechanical, biocompatibility, and magnetic resonance testing to verify that the devices met the specifications. The devices met the specifications and the materials did not elicit toxicological responses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2002

Rita Medical Systems
Karen Frischmeyer
Director, Clinical Programs
967 North Shoreline Boulevard
Mountain View, California 94043

Re: K023846
Trade/Device Name: MR Compatible Model 90 Electrosurgical Probe
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation accessory
Regulatory Class: Class II
Product Code: GEI
Dated: November 18, 2002
Received: November 19, 2002

Dear Ms. Frischmeyer:

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 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), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 INTENDED USE

Indications for Use Statement

510(K) Number (if known) K023846

Device Name MR Compatible Model 90 Electrosurgical Probe

The MR Compatible Model 90 Electrosurgical Probe is designed to supply energy (generated by the RITA Medical Systems' electrosurgical generator) for use in electrosurgery and is designed for the following:

- Incorporation of multiple needles on each probe minimizing the number of invasive accesses necessary to achieve desired lesions.
- Provide a minimally invasive laparoscopic, percutaneous, or intraoperative access to the targeted tissue.
- Deliver radiofrequency energy in a controlled fashion to create coagulative necrotic lesions.
- Incorporate thermocouples for temperature feedback.
- Provide for local delivery of fluid.

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____

(per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K023846