APR 2 8 2004

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K040989

Applicant	RITA Medical Systems, Inc. 967 N. Shoreline Blvd. Mountain View, CA 94043
Contact Person	Darrin Uecker Telephone Number: (650) 314-3433 Fax Number: (650) 390-8505
General Provisions	Trade Name: RITA® System Common/Classification Name: Electrosurgical cutting and coagulation device
Name of Predicate	RITA Medical Systems Inc. – RITA System
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 RITA® System (RF generator and electrosurgical devices) supplies energy for use in electrosurgery and is indicated for use in percutaneous, laparoscopic, or intraoperative coagulation and ablation of soft tissue, including the partial or complete ablation of non-resectable liver lesions and the palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard pain therapy.
Device Description	The RITA System consists of the following components: **RF Generator:** Provides RF energy to the Device through the Main Cable. **Disposable Electrode ("the Device"):** Consists of a number of deployable electrodes. Some or all are equipped with a thermocouple, depending on the model of the Device. Some Devices are used with saline infusion ("Infusion Devices") and require the use of a pump. **Infusion Pump:** When using the RF Generator with the Infusion Devices, an off-the-shelf market-cleared infusion pump or a RITA Pump is used to deliver saline through the Infusion Device during ablation. In the off-the-shelf pump, syringes are connected to the Infusion Device and loaded into the Infusion Pump. In the RITA Pump, a Tubing Kit is connected to the Infusion Device and loaded into the RITA Pump. The RF Generator is connected to the Infusion Pump via an RS-232 cable. **Tubing Kit:** The tubing kit is designed to load into the pump head from the front of the pump. On the proximal end of the tubing-set there is a PVC Bag Spike fitting that allows the tubing to be attached to an IV bag. The Bag Spike fitting is attached to a single length of tubing that is connected to a splitter fitting that splits the single tubing into 5 separate tubes. The 5 tubes are held together with clips that allow the tubes to be uniformly loaded into the pump head. The distal end on the tubing-set has 5 female luers to attach to the Infusible devices. **Main Cable:** Connects the Device to the RF Generator.

Dispersive Electrode: Provides the return path for the RF energy applied by the Device. Depending on the model, the dispersive electrode may be equipped with thermocouples to measure skin temperature at the dispersive pad. Dispersive pads with temperature sensing capabilities are connected to the RF Generator at the dispersive electrode connection and at the Aux port.

Power Cord: A medical grade line cord that provides AC power to the RF Generator.

Foot Pedal: The Foot Pedal is connected to the front of the RF Generator. The Foot Pedal starts and stops the RF energy delivery when the RF Generator is in "READY" mode.

Device Description (cont.)

To use the system, the RF Generator is plugged into the wall outlet via the Power Cord. The electrosurgical device is connected to the RF Generator via the Main Cable. The Dispersive Electrode is placed on the appropriate location of the body and is connected to its port on the RF Generator. If a pump is used, it is connected to serial port B of the RF Generator. Once the system is successfully powered up, the user can set the parameters of the ablation such as the mode of operation, the ablation time, the target temperature, and the power delivery level. One mode of operation, purge, is used to communicate with an infusion pump to prime the system. There are four modes of operation for RF energy delivery: constant power, constant temperature, infusion mode, and track ablation. In the infusion mode, the RF Generator communicates with the infusion pump to set and adjust the infusion rate. With the electrosurgical device placed in the tissue to be ablated and its electrodes deployed, RF power can be turned on. The system parameters are continuously monitored and displayed on the RF Generator. If the measured parameters are outside the acceptable limits, the RF energy delivery and fluid delivery (if in infusion mode) automatically stops and a message appears on the liquid crystal display (LCD). The RF energy delivery and fluid delivery (if in infusion mode) also automatically ceases once the ablation is completed based on the initial user-defined parameters. RF energy can also be stopped at any point by pressing the RF on/off switch. Fluid delivery can also be stopped at any point by pressing the pump on/off switch.

Performance Data

The RITA System is subjected to design verification, software validation, ablation performance, and sterilization validation testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2004

RITA Medical Systems, Inc.
c/o Mr. Morten Christensen
Underwriters Laboratories, Inc.
1655 Scott Boulevard
Santa Clara, California 95050

Re: K040989
Trade/Device Name: RITA System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 14, 2004
Received: April 16, 2004

Dear Mr. Christensen:

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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

Miriam C. Provost

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

Enclosure

Indications for Use

510(k) Number (if known): K040989

Device Name: **RITA System**

Indications for Use:

The RITA® System (RF generator and electrosurgical devices) supplies energy for use in electrosurgery and is indicated for use in percutaneous, laparoscopic, or intraoperative coagulation and ablation of soft tissue, including:

- the partial or complete ablation of non-resectable liver lesions and
- the palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard pain therapy.

Prescription Use ✓ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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