510(k) Summary of Safety and Effectiveness

General Provisions	Trade Name: RITA® Model 500 Electrosurgical RF Generator and Accessories Common/Classification Name: Electrosurgical cutting and coagulation devices
Name of Predicate	RITA Medical Systems Inc. – Model 10 Electrosurgical Accessory RITA Medical Systems Inc. – Model 500 Electrosurgical RF Generator RITA Medical Systems Inc. – Models 20 and 30 Electrosurgical Accessories RITA Medical Systems Inc. – Model 30F Electrosurgical Probe RITA Medical Systems Inc. – Model 200C Electrosurgical Probe RITA Medical Systems Inc. – Model 30-6 Electrode Array Electrosurgical Probe RITA Medical Systems Inc. – Model 10P Passive Temperature Probe Accessory
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 (Model 500 RF Generator and Accessories) supplies energy for use in electrosurgery, and are 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.
Device Description	The RITA Model 500 Electrosurgical Generator and Accessories are designed to create coagulative necrotic lesions in soft tissue, and allow localized delivery of fluid to the lesion. The RF Generator is specifically designed for use with RITA Electrosurgical Devices (Accessories). The RF Generator provides multiple temperature sensors, impedance, and power monitoring to assist the user in delivering the desired energy to the target tissue. The Accessories consist of monopolar electrosurgical devices that include disposable electrosurgical probes with deployable needle arrays that deliver RF power with temperature and impedance monitoring to ablate predictable volumes of tissue.
Performance Data	Clinical studies were conducted to determine the safety and effectiveness of the RITA System for the ablation of cancerous liver lesions. In one study, lesions were ablated in patients who were scheduled for surgical resection. In other studies, the RITA System was used for the ablation of cancerous liver lesions (primary and metastatic) in patients whose liver cancer was considered to be non-resectable. The non-resectable lesion studies demonstrated that the ablation procedure had low attendant morbidity (no reports of death related to use of the devices) and a low adverse event rate. All of the studies demonstrated that, in general, the diameter of a single ablation consistently averaged 3-4 cm (as determined by post procedure CT scans).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 2000

Ms. Erin Dignan-Mazzone
Director, Regulatory Affairs
RITA Medical Systems, Inc.
967 North Shoreline Boulevard
Mountain View, California 94043

Re: K983214
Trade Name: RITA RF generator and Accessories, Model 500 series
Dated: January 14, 2000
Received: January 18, 2000

Dear Ms. Dignan-Mazzone:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

Although this device is substantially equivalent to other devices used for ablation of soft tissue, we are concerned that users may overestimate the capability of the device. It is on this basis that we are requesting that you include the following statement in the precautions section of the labeling:

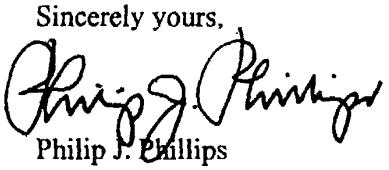
The effectiveness of this device for use in the treatment of liver cancer or liver disease (i.e., improved clinical outcomes) has not been established.

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, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), 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"(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/dsma/dsmamain.html".

Sincerely yours,



Philip J. Phillips
Deputy Director
Science and Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K983214

Device Name: RITA RF generator and Accessories, Model 500 series

FDA's Statement of the Indications For Use for device:

The RITA System (Model 500 RF Generator and Accessories) supplies energy for use in electrosurgery, and are 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.

3-27-00

Prescription Use XXXX OR Over-The-Counter Use ____
(Per 21 CFR 801.109)