DEC 1 1998

Attachment 4 Summary of Safety and Effectiveness

K983871

Summary of Safety and Effectiveness

General Provisions	Trade Name: Model 70 Electrosurgical Probe Common/Classification Name: Electrosurgical Cutting and Coagulation Accessory
Name of Predicate Devices	RITA Medical Systems Inc. - Model 30 Electrosurgical Probe
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 and Device Description	The Model 70 Electrosurgical Probe is designed to supply energy (generated by the RITA Medical Systems' Model 500 Electrosurgical Generator) for use in elec for the following:

Scan

- Incorporation of multiple needles on number of invasive accesses necessa lesions.
- Provide a minimally invasive laparo 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.

The device description of the Model 70 Electrosurgical Probe is as follows:

This RITA device is available in 15 cm and 25 cm lengths for a variety of medical applications. The secondary electrodes deploy forming a spherical lesion 3 centimeters in diameter. The RITA device consists of the following components:

- *primary electrode*: stainless-steel hypodermic tubing with a portion exposed as an electrode
- *secondary electrodes*: stainless-steel extendible flexible hypodermic tubing at the distal end of probe
- *trocar insulation*: fixed clear polyester shrink tubing
- *handle*: PVC and ABS with markings to indicate the amount of electrode array deployment from the trocar
- *RF pathway*: connection through 6 pin Lemo connector built into the handle
- *fluid infusion*: delivery through Luer port at side of the handle
- *temperature sensors*: 4 temperature sensors at the periphery of the array
- *depth indicators*: Incremental 1 cm marks denote needle penetration depth

Biocompatability

All materials used in the Model 70 Electrosurgical Probe are Biocompatible.

Summary of Substantial Equivalence

The Model 70 Electrosurgical Probe is substantially equivalent to the previously cleared Model 30 Electrosurgical Probes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1998

Mr. David A. Tucker
Vice President of Quality Assurance and Regulatory Affairs
RITA Medical Systems, Inc.
967 North Shoreline Boulevard
Mountain View, California 94043

Re: K983871
Trade Name: RITA Model 70 Electrosurgical Probe
Regulatory Class: II
Product Code: GEI
Dated: October 30, 1998
Received: November 2, 1998

Dear Mr. Tucker:

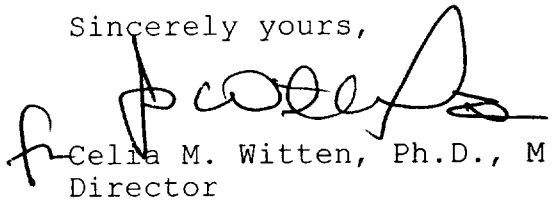
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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. 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 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 requirement, 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.

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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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,



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

Enclosure

[redacted]

Attachment 2 Indications for Use Statement

Indications for Use Statement

510(K) Number (if known) K983871

Device Name: Model 70 Electrosurgical Probe

Indication for Use: The Model 70 Electrosurgical Probe is designed to supply energy (generated by the RITA Medical Systems' Model 500 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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983871

Prescription Use X OR Over the Counter Use _____
(per 21 CFR 801.109)