K992693

8.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

General Provisions	Trade Name: Model 90 Electrosurgical Probe Common/Classification Name: Electrosurgical cutting and coagulation accessory
Name of Predicate	RITA Medical Systems Inc. - Model 70 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	The 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® 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 Model 90 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 polymer 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 Model 90 devices were subjected to a battery of electrical, mechanical, and biocompatibility 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

SEP 10 1999

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

Re: K992693
Trade Name: RITA Model 90 Electrosurgical Accessory
Regulatory Class: II
Product Code: GEI
Dated: August 10, 1999
Received: August 12, 1999

Dear Ms. Dignan:

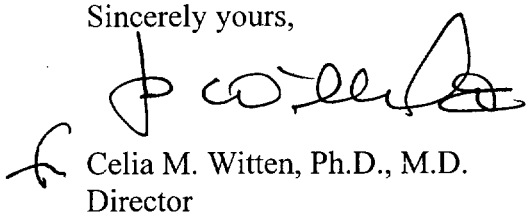
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

3.0 INTENDED USE

Indications for Use Statement

510(K) Number (if known) K992693

Device Name Model 90 Electrosurgical Probe

The 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)

(Division Sign-Off)
Division of General Restorative Devices K992693
510(k) Number

Prescription Use ✓ OR Over the Counter Use _____

(per 21 CFR 801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 1999

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

Re: K992693
Trade Name: RITA Model 90 Electrosurgical Accessory
Regulatory Class: II
Product Code: GEI
Dated: August 10, 1999
Received: August 12, 1999

Dear Ms. Dignan:

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

3.0 INTENDED USE

Indications for Use Statement

510(K) Number (if known) K992693

Device Name Model 90 Electrosurgical Probe

The 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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992693

Prescription Use ✓ OR Over the Counter Use _____

(per 21 CFR 801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food And Drug Administration

Memorandu

From: Reviewer(s) - Name(s)

Subject: 510(k) Number K992693

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☐ Accepted for review 8/19/99.
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☒ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive	☐ YES	☐ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☐ The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin ☐ YES ☐ NO

79 GEI + Class II

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class:	Additional Product Code(s) with panel (optional):
	79 GEI (Electrosurgical Device, Cutting & Coagulation & Accessories), Class II

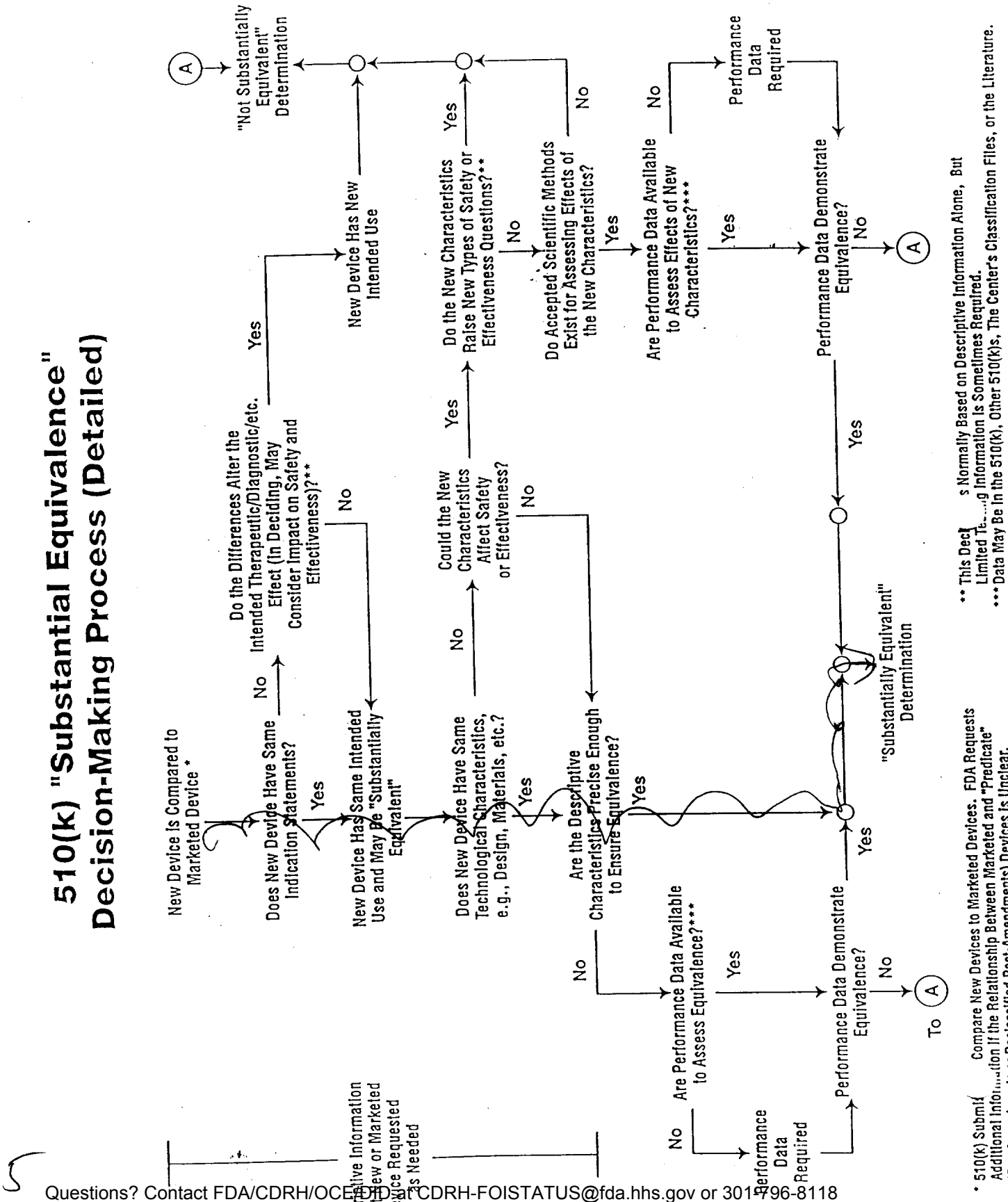
Review: Neil R.P. Ogden (Branch Chief) GSDB (Branch Code) 9/3/99 (Date)

Final Review: (Division Director) 9/10/99 (Date)

Revised:6/2//98

4

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name: RITA Model 90 Electrosurgical Accessory | K 992693

Submitter (Company): RITA Medical Systems INC.

Items which should be included *(circle missing & needed information)*	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,3		GO TO # 2,4,5		GO TO #2 4,5		

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	NA SPECIALS YES	NA SPECIALS NO	YES ABBREVIATED	YES ABBREVIATED NO	NO TRADITIONAL YES	NO TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
a) trade name, classification name, establishment registration number, device class	✓						
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA						
d) compliance with Section 514 - performance standards	NA						
e) address of manufacturer	✓						
f) Truthful and Accurate Statement	✓						
g) Indications for Use enclosure	✓						
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*	✓						
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*	✓						
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals	✓						
k) Proposed Labeling:	✓						
i) package labeling (user info)	✓						
ii) statement of intended use	✓						
iii) advertisements or promotional materials	✓						
i) MRI compatibility (if claimed)	N/A						
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:							
i) Labeling	✓						
ii) intended use	✓						
iii) physical characteristics	✓						
iv) anatomical sites of use	✓						
v) performance (bench, animal, clinical) testing	NA						
vi) safety characteristics	NA						
m) If kit, kit certification	N/A						

3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II , III OR RESERVED CLASS I DEVICE				
a) Name & 510(k) number of legally marketed (unmodified) predicate device	✓			
b) *STATEMENT - INTENDED USE AND INDICATIONS FOR*	✓		* If no - STOP not a special	6

USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				
c) ***STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED****			* If no - STOP not a special	
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

inapplicable requirements or deviations noted below						
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed						
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device						
v) A specification of any deviations from each applicable standard that were applied						
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference						
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations						
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards						

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ✓ **Yes** ____ **No**
Date: 8/19/99

Reviewer: George J. Mathamel
Concurrence by Review Branch: DGRD/GSDB.

8

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 992693

Reviewer: GEORGE J. MATTAMAL

Division/Branch: DGRD / GSDB

Device Name: RITA Model 90 Electronyzid Recovery

Product To Which Compared (510(K) Number If Known): K983871

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	✓		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		✓ ✗
3. Have you verified that the Document is labeled Class III for GMP purposes? 4. If, not, has POS been notified?		
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?	✓ ✓	✗
8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✗
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		✗

To: THE FILE RE: DOCUMENT NUMBER K 992693

DATE: August 31, 1999. **OFFICE:** HFZ-410

FROM: Polymer Chemist **DIVISION:** DGRD/GSDB

DEVICE NAME: RITA Model 90 Electrosurgical Accessory
COMPANY NAME: RITA Medical Systems, Inc.

CONTACT: Ms. Erin Dignan, Director, Regulatory Affairs
&
Mr. Dan Balbierz, Vice President, Quality Assurance and Regulatory Affairs
(Tel. No. 650-390-8500, Ext. 239 & Fax. 650-390-8505)

The 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Reserved Class I device. The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device: **RITA Model 70 Electrosurgical Accessory (K983871).**
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, substantial equivalence comparison table of the subject and predicate devices in terms the number of electrodes arrays, number of thermocouples, connector, outer diameter of the electrodes, etc.
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

6. A Truthful and Accurate Statement, a 510(k) Summary of Safety and Effectiveness and the Indications for Use are provided.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed.

RECOMMENDATION: The submitter has provided the design control information as specified in the New 510(k) Paradigm and on this basis, I recommend the subject device, "RITA Model 90 Electrosurgical Accessory", be determined substantially equivalent to the previously cleared their own predicate device, the original RITA Model 70 Electrosurgical Accessory (K983871). The device is associated with the electrosurgical surgery and is categorized as 79 GEI (Electrosurgical Device, Cutting & Coagulation and Accessories). And the device is class II based on 21 CFR 878.4400.

George J. Mattamal 8/31/99

(Reviewer's Signature) (Date)

George J. Mattamal, Ph.D.
General and surgery Devices Branch
Division of General Restorative devices

Concur with SE.
9/3/99

CONTACT HISTORY: The sponsor (Mr. Dan Balbierz) was contacted on 8/31/99 to learn more about the device.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 16, 1999

RITA MEDICAL SYSTEMS
967 NORTH SHORELINE BLVD.
MOUNTAIN VIEW, CA 94043
ATTN: ERIN DIGNAN

510(k) Number: K992693
Received: 12-AUG-1999
Product: RITA MODEL 90
ELECTROSURGICAL
ACCESSORY, MODEL 90

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

13

 K992693

RITA
MEDICAL SYSTEMS, INC.

Special 510(k): Device Modification

August 10, 1999

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Reference 1: K983871 Model 70 Electrosurgical Accessory, concurrence received on 12/1/98.

Dear Sir or Madam:

In accordance with Section 510(k) of the Food, Drug, and Cosmetic Act, and in conformance with 21 CFR 807, RITA Medical Systems, Inc. is submitting this premarket notification proposing to introduce into commerce a modification to a device that has been previous cleared by the FDA. The modifications to the electrosurgical electrode accessory include: changes to the dimensions, a change in a material, and the addition of a fifth thermocouple sensor. These modifications are eligible for the **Special 510(k) process** as they have the same scientific technology and the same intended use as the predicate device.

STATEMENT OF CONFIDENTIALITY: RITA Medical Systems considers the information described in this letter and in the submission, itself, to be confidential commercial information, and therefore exempt from public disclosure. Consequently, we request that this notification be treated as confidential in accordance with 21 CFR 20.61b. All documents containing proprietary information are marked "Confidential".

STATEMENT OF SUBSTANTIAL EQUIVALENCE: The terms "substantial equivalence" and "predicate device" as used in this premarket notification are intended only to demonstrate equivalence to the predicate product for purposes of obtaining clearance of the device pursuant to the Food, Drug and Cosmetic Act. Reference to the equivalence as outlined in this submission is in no way related to the term "equivalent" or similar terminology as outlined under the patent laws.

This submission is contained in one volume. Two original copies of the submission are included for your review. If you have any questions regarding this notification or require additional information, please do not hesitate to contact me at (650) 390-8500 x239.

Respectfully submitted,

Erin Dignan

Erin Dignan
Director, Regulatory Affairs
RITA Medical Systems, Inc.

Enclosure: Two original copies of "Special 510(k)" submission

5U
II
14

5/10

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: August 10, 1999 | FDA Document Number:

Section A — Type of Submission

- ☒ 510(k)
- ☐ 510(k) Add'l information
- ☐ IDE
- ☐ IDE Amendment
- ☐ IDE Supplement
- ☐ IDE Report
- ☐ PMA
- ☐ PMA Amendment
- ☐ PMA Report
- ☐ PMA Supplement - Regular
- ☐ PMA Supplement - Special
- ☐ PMA Supplement - 30 day
- ☐ PMA Supplement - Panel Track

Section B1 — Reason for Submission - 510(k)s Only

- ☐ New device
- ☐ Additional or expanded indications
- ☒ Change in technology, design, materials or manufacturing process
- ☒ Other reason (specify): **Special 510(k)**

Section B2 — Reason for Submission - PMAs Only

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Labeling Changes:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Change in ownership
- ☐ Change in correspondent
- ☐ Other reason (specify):
- ☐ Change in design, component or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Other (specify below)
- ☐ Process change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Response to FDA correspondence (specify below)
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for an extension
- ☐ Request to remove or add a manufacturing site
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment

Section B3 — Reason for Submission - IDEs Only

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion/extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing
  - ☐ Protocol - feasibility
  - ☐ Protocol - other
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approval
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting
- ☐ Emergency use:
  - ☐ Notification of emergency use
  - ☐ Additional information
- ☐ Other reason (specify):
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ IOL submissions only:
  - ☐ Change in IOL style
  - ☐ Request for protocol waiver

15

FDA Document Number:

Section C — Product Classification

Product code: GEI	C.F.R. Section: 878.4400	Device Class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification Panel: General and Plastic Surgery		

Section D — Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1. GEI	2.	3.	4.
5.	6.	7.	8.

Summary of, or statement concerning, safety and effectiveness data:
☒ 510(k) summary attached
☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1. K983871	1. RITA Model 70 Electrosurgical Accessory	1. RITA Medical Systems, Inc.
2.	2.	2.

Section E — Product Information - Applicable to All Applications

Common or usual or classification name: Electrosurgical Accessory

Trade or proprietary or model name	Model Number
1. RITA Model 90 Electrosurgical Accessory	1. 90
2.	2.
3.	3.
4.	4.
5.	5.
6.	6.
7.	7.
8.	8.
9.	9.

FDA document numbers of all prior related submissions (regardless of outcome):

1.	2.	3.	4.	5.	6.
7.	8.	9.	10.	11.	12.

Data included in this submission: ☐ Laboratory testing ☐ Animal trials ☐ Human trials

Indications (from labeling):

The Model 90 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.

FDA Document Number:

Section F — Manufacturing / Packaging / Sterilization Sites

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 2952363	☒ Manufacturer ☐ Contract manufacturer	☐ Contract Sterilizer ☐ Repackager / relabeler
Company / Institution name: RITA Medical Systems, Inc.			
Division name (if applicable):		Phone number (include area code): (650) 390-8500 x239	
Street address: 967 N. Shoreline Blvd.		FAX number (include area code): (650) 390-8505	
City: Mountain View	State / Province: CA	Country: USA	ZIP / Postal Code: 94043
Contact name: Erin Dignan			
Contact title: Director, Regulatory Affairs			
☒ Original ☐ Add ☐ Delete	FDA establishment registration number: (b)(4)	☐ Manufacturer ☐ Contract manufacturer	☒ Contract Sterilizer ☐ Repackager / relabeler

(b) (4) [redacted]

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract Sterilizer ☐ Repackager / relabeler
Company / Institution name:			
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

FDA Document Number:			
Section G	**Applicant or Sponsor**		
Company / Institution name: RITA Medical Systems, Inc.			FDA establishment registration number: 2952363
Division name (if applicable):			Phone number (include area code): (650) 390-8500 x239
Street address: 967 N. Shoreline Blvd.			FAX number (include area code): (650) 390-8505
City: Mountain View	State / Province: CA	Country: USA	ZIP / Postal Code: 94043
Signature: Erin Dignan			
Name: Erin Dignan			
Title: Director, Regulatory Affairs			
Section H	**Submission correspondent (if different from above)**		
Company / Institution name:			
Division name (if applicable):			Phone number (include area code): ( )
Street address:			FAX number (include area code): ( )
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have questions concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

Premarket Notification – Special (510(k)): Device Modification

for the

Model 90 Electrosurgical Accessory

RITA Medical Systems, Inc.

August 10, 1999

Table of Contents

30

1.0 TRUTHFUL AND ACCURACY STATEMENT

Pursuant to 21 CFR 807.87(j), I, Erin Dignan, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Director of Regulatory Affairs at RITA Medical Systems, Inc., and in reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.

Erin Dignan — Aug 9, 1999

Erin Dignan
Director, Regulatory Affairs
RITA Medical Systems, Inc.

Date

2.0 GENERAL INFORMATION

2.1 APPLICANT

Applicant: RITA Medical Systems, Inc.
967 North Shoreline Blvd.
Mountain View, CA 94043

Contact Person: **Erin Dignan**
Telephone Number: **(650) 390-8500 x239**
Secondary Contact Person: Dan Balbierz
Telephone Number: (650) 390-8500 x222
Fax Number: (650) 390-8505

2.2 DEVICE NAME

RITA® Model 90 Electrosurgical Probe

The device classification name is the same as listed in 510(k) K983871: Electrosurgical Cutting and Coagulation Accessory.

2.3 ADDRESS AND REGISTRATION NUMBERS

2.3.1 Manufacturing Facility Address

The manufacturing facility listed in K983871 has remained unchanged.

Manufacturer: RITA Medical Systems, Inc.
967 North Shoreline Blvd.
Mountain View, CA 94043

2.3.2 Manufacturing Registration Number

The Establishment Registration Number is 2952363, which is unchanged from K983871.

2.4 STERILIZATION FACILITY ADDRESS

(b) (4) [redacted]

2.5 DEVICE CLASSIFICATION

Electrosurgical cutting and coagulation accessories have been classified as Class II Product Code GEI under Section 514 of the Food, Drug, and Cosmetic Act.

No performance standards have been established under Section 514 of the Act.

3.0 INTENDED USE

Indications for Use Statement

510(K) Number (if known) K992693

Device Name Model 90 Electrosurgical Probe

The 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)

4.0 LABELING

Just like the intended use, the labeling remains unchanged, except for the new model name. The following are **draft versions** of labels and Instructions for Use.

Model 90, 25 cm Device, Box and Tray Labels

Model 90, 15 cm Device, Box and Tray Labels

Model 90 Instructions for Use

RITA MEDICAL SYSTEMS, INC.

DRAFT

Model 90 Electrosurgical Device

INDICATIONS: FOR TISSUE COAGULATION ONLY

FOR USE WITH THE RITA® RF GENERATOR ONLY

INSTRUCTIONS FOR USE:
After all patient preparation has been completed, the Dispersive Electrodes (2 required) have been applied according to the package instructions, and the RF Generator controls have been set to the desired settings. the following is the recommended procedure for operating the RITA® Model 90 Device:

1. Under sterile conditions, peel back Tyvek from tray and remove the RITA Device.
2. Inspect Device prior to use. If the Device is damaged, do not use.
3. Before inserting the Device, fully retract the electrodes by holding the main body in place and pulling on the deployment shaft disk.
4. If fluid delivery is desired, remove the luer cap and attach a syringe, and prime with appropriate solution.
5. Using ultrasound guidance, place the Device by holding along the main body. Do not hold the deployment shaft handle during placement, as this could inadvertently cause deployment of the array. The tip of the trocar should be placed approximately 1cm proximal to the center of the target area.
6. After Device placement is complete, deploy the electrodes slowly by holding the main body in place (with light forward pressure) and pushing on the deployment shaft disk. (Monitor deployment on ultrasound to ensure that it is deployed properly into the intended area.)
7. Connect one end of the Main Cable to the Device and the other end to the Generator.
8. Use a single Device for a maximum of four ablations.

⚠	Attention, consult accompanying documents	LOT	Batch Code
2	Do Not Reuse	STERILE R	Method of Sterilization
	Use By:	CE 0044	CE Mark: Indicates that the essential requirements of all relevant European Union directives are fulfilled.

In United States:

RITA Medical Systems, Inc.
967 N. Shoreline Blvd.
Mountain View CA 94043
Telephone: 650-390-8500
Fax: 650-390-8505

In Italy and Switzerland:

M.D.H. s.r.l. Forniture Ospedaliere
Via delle Gardenie, 9
20147 MILANO Italy
Telephone: 011-39-02-4159993
Fax: 011-39-02-417875

5.0 DEVICE DESCRIPTION

5.1 DESCRIPTION

This RITA device is available in 15-cm and 25-cm lengths for a variety of medical applications. The secondary electrodes deploy out (up to approximately 4 cm) from the trocar tip. 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*: K-resin and ABS with markings to indicate the amount of electrode array deployment from the trocar
- *RF pathway*: connection through nine-pin 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

5.2 DISCUSSION OF MODIFICATIONS

The predicate Model 70 device is used to transfer RF energy in the creation of necrotic lesions, using seven extendable electrodes (arrays) made of 304 stainless steel. The Model 90 device is used to transfer RF energy in the creation of necrotic lesions, using nine extendable electrodes (arrays) made of 304 stainless steel.

The change (b) (4) [redacted]

The material of the main body of the handle of the Model 90 (b) (4) [redacted] Additionally, the material of the nose cone of the handle was changed from PVC to a new material, K-resin. This material was chosen for its clear appearance before and after e-beam sterilization.

6.0 SUBSTANTIAL EQUIVALENCE

6.1 COMPARISON

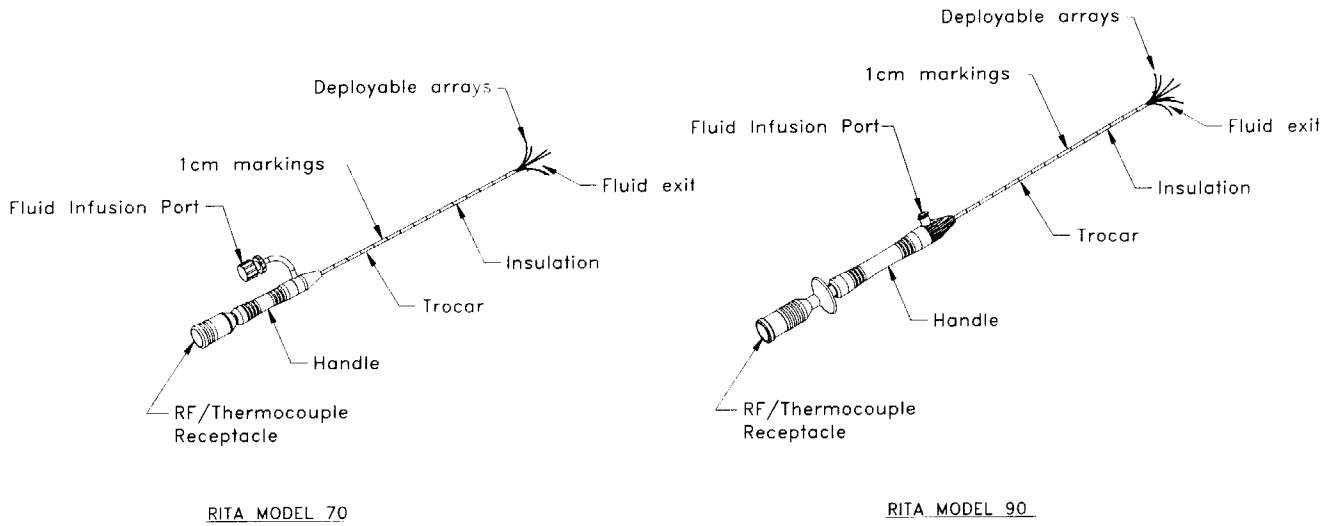


Figure 5-1: Device Diagram

Figure 5-1 is a pictorial comparison the Model 90 to the predicate device (Model 70).

Table 5-1 compares the Model 90 to the predicate device (Model 70) in more detail. Note that the shaded areas highlight dimensional and material changes between the two devices.

Table 5-1: Product Comparison Table

Feature	RITA Medical Systems	
	Model 70	**Model 90**
510(k) #	K983871	To be assigned
Intended Use	To supply energy (generated by the RITA Medical Systems' Model 500 electrosurgical generator) for use in electrosurgery.	To supply energy (generated by the RITA Medical Systems' Model 500 electrosurgical generator) for use in electrosurgery.
Number of electrode arrays	7 †	(b) (4)
Array Material	304 Stainless Steel	304 Stainless Steel
Array Wire Outer Diameter	0.016 inches	0.016 inches
RF Coagulation	Yes	Yes
Insulation on Electrode	Yes	Yes
Thermocouples on Arrays	Yes	Yes
Number of Thermocouples	4	(b) (4)
RF Delivery	Monopolar	Monopolar
Connector	6 pin Lemo	(b) (4)
Outer Diameter	15 Ga.	
Handle Material(s)	PVC & ABS	
Useable Length	15 cm & 25 cm	15 cm & 25 cm
Fluid Infusion Port	Yes	Yes
Available Lengths	15 cm & 25 cm	15 cm & 25 cm
Sterilization	Electron Beam	Electron Beam

(b) (4)

6.2 SUMMARY

In summary, the modified Model 90 Electrosurgical Probe has the following similarities to the Model 70 Electrosurgical Probe, which has previously received 510(k) clearance:

- Has the same intended use,
- Uses the same operating principle,
- Incorporates the same basic electrosurgical probe design,
- Can create comparable lesions,
- Incorporates most of the same materials,
- Has the same shelf life, and
- Is packaged and sterilized using the same materials and processes.

Thus, the Model 90 Electrosurgical Probe described in this submission is, in our opinion, substantially equivalent to the predicate device.

7.0 DESIGN CONTROLS

7.1 SUMMARY OF DESIGN CONTROL ACTIVITIES

The risk analysis method used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA). The design verification tests that were performed as a result of this risk analysis assessment are listed in **Table 7-1**. The Spherical Lesion Test was done to verify that size and shape of the lesions are comparable to that of the previous device. Testing to verify conformance to AMMI/ANSI HF – 18 and IEC 601-2-2 was conducted. The array dimensions were verified. Sharpness was assessed to ensure smooth tissue penetration. Echogenicity was verified under ultrasound. Extraction forces were evaluated to ensure that the electrode could be extracted with minimal tissue trauma, in the unlikely event that the arrays would not retract. Leakage and flow rate testing was conducted on the fluid infusion port. The strength of the array joints was tested to ensure arrays are firmly attached to the body of the device. Finally, biocompatibility testing was performed on the new material. Biocompatibility testing was not repeated for the other materials since they are the same as those used in the Model 70 device.

Table 7-1: Design Verification Tests

Test	Test Sample	Acceptance Criteria	Results
(b) (4)			

7.2 DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

Verification Activities

All verification activities, as required by the risk analysis, were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Dan Balbierz
VP, Research and Development

8/10/99
Date

Manufacturing Facility

The manufacturing facility, RITA Medical Systems, Inc. is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

Ron Steckel
VP, Operations and Quality Assurance

8/10/99
Date

K992693

8.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

General Provisions	Trade Name: Model 90 Electrosurgical Probe Common/Classification Name: Electrosurgical cutting and coagulation accessory
Name of Predicate	RITA Medical Systems Inc. - Model 70 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	The 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® 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 Model 90 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 polymer 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 Model 90 devices were subjected to a battery of electrical, mechanical, and biocompatibility testing to verify that the devices met the specifications. The devices met the specifications and the materials did not elicit toxicological responses.