9.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K030936

Contact Information	RITA Medical Systems 967 N. Shoreline Blvd. Mountain View, CA 94043 Phone: 650 314-3400 Fax: 650 890-3905 Contact Person: Vicki Hacker, VP of Clinical Affairs
General Provisions	Trade Name: RITA® Clips Common/Classification Name: Infusion Pump Accessory
Name of Predicate Device	Harvard Clinical Technology – Harvard 2 Syringe Pump
Classification	Class II
Performance Standards	Performance standards have not been established for infusion pump accessory (syringe holder) under section 514 of the Food, Drug and Cosmetic Act.
Intended Use	The RITA® Clips are used with Harvard 2 Syringe Pump to increase the syringe holding capacity of the Pump from two to five syringes to allow one Harvard 2 Syringe Pump to supply local delivery of saline through multiple irrigation ports of one RITA® Electrosurgical Device of the RITA® System. The RITA® System is intended 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® Clips are a syringe holder accessory to the Harvard 2 Syringe Pump to accommodate five (5) 20-cc syringes.
Performance Data	The RITA® Clips and Harvard 2 Syringe Pump underwent testing to verify flow rate and alarm function. The devices passed the test criteria. The RITA® Clips do not directly contact the patient therefore no biocompatibility testing was required.

APR 0 1 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 01 2003

RITA Medical Systems Incorporated
C/O Mr. Charles Mack
Responsible Third Party Official
Underwriters Laboratories Incorporated
2600 N.W. Lake Road
Camas, Washington 98601-8542

Re: K030936
Trade/Device Name: RITA ® Clips for Infusion Pumps
Regulation Number: 880.5725
Regulation Name: Infusion Pump Accessory
Regulatory Class: II
Product Code: MRZ
Dated: March 19, 2003
Received: March 25, 2003

Dear Mr. Mack:

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) 594-4618. 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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental 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)

Device Name RITA® Clips for Infusion Pumps

The RITA® Clips are used with Harvard 2 Syringe Pump to increase the syringe holding capacity of the Pump from two to five syringes to allow one Harvard 2 Syringe Pump to supply local delivery of saline through multiple irrigation ports of one RITA® Electrosurgical Device of the RITA® System. The RITA System is intended for use in percutaneous, laparoscopic, or intraoperative coagulation and ablation of soft tissue, including the partial or complete ablation of non-resectable liver lesions.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21 CFR 801). OR Over the Counter Use _____

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K030936