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SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Cool-tip™ RF Ablation System

K042216

1. Submitter Information

Valleylab
A division of Tyco Healthcare Group LP
5920 Longbow Drive
Boulder, CO 80301
Contact: Charles M. Copperberg
Manager, Regulatory
Telephone: 303-530-6247

Date summary prepared: August 13, 2004

2. Name of Device

Trade or Proprietary Name: Cool-tip™ RF Ablation System

Common/Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories

3. Predicate Devices

The Cool-tip™ RF Ablation System is substantially equivalent to the following legally marketed medical devices:

- ✓ Cool-tip™ RF Ablation System (K984552)
- ✓ RITA Medical Systems RF Generator and Accessories (K993944, K021329, K031257 and K031926)
- ✓ RadioTherapeutics RF Generator and LeVeen Electrode (K012315 and K000241)

4. Device Description

The Cool-tip™ RF Ablation System consists of a microprocessor based RF generator, a peristaltic pump, electrodes, inflow and outflow tubing for electrode cooling, and return pads. The generator, pump and electrodes are designed to produce local tissue heating at the tip of the electrodes causing the coagulation (ablation) of the tissue.

The Cool-tip™ RF Ablation System generator is capable of delivering up to 200 watts (into a 50 Ohm resistive load) while monitoring tissue impedance and electrode tip temperature during the delivery of the RF energy. The generator includes manual and impedance control and displays/monitors impedance, current, power and temperature.

The Cool-tip™ electrodes are available in either a single electrode or a cluster electrode configuration. The electrodes are monopolar devices. The cluster electrode is three electrode shafts combined into one handle in a triangular patter with approximately 0.5 cm. separation. The electrodes are provided sterile, for single use only. The shaft of the electrode is stainless steel that is insulated to various lengths from the tip of the electrode. Embedded within the tip of each electrode is a thermocouple for temperature measurement. Cooling of the electrode is provided by chilled sterile water which is pumped (using the peristaltic pump) through the inflow tubing, the electrode and out through the outflow tubing. This is an enclosed system within the electrode and the sterile water does not contact the patient. Because of the monopolar nature of the electrodes, electrical current flows through the tip of the electrode, through the target tissue and to the return pad.

5. Intended Use

The Cool-tip™ RF Ablation System (Generator and Accessories) is intended for use in percutaneous, laparoscopic and intraoperative coagulation and ablation of tissue, such as partial or complete ablation of non-resectable liver lesions.

6. Summary of Technological Characteristics

The Cool-tip™ RF Ablation System has the same basic technological characteristics as the predicate devices noted above.

7. Performance and Clinical Data

Comparative in vivo and ex vivo product testing has shown the Cool-tip™ RF Ablation System to be equivalent to currently marketed devices with regard to coagulation/ablation of lesions. Independent clinical studies have shown the use of the system to be clinically safe and effective for ablation of non-resectable liver lesions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2004

Mr. Charles M. Copperberg
Manager, Regulatory
Valleylab
A Division of Tyco Healthcare Group LP
5920 Longbow Drive
Boulder, Colorado 80301

Re: K042216
Trade/Device Name: Cool-tip™ RF Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 13, 2004
Received: August 16, 2004

Dear Mr. Copperberg:

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 (240) 276-0115. 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

510(k) Number (if known): K042216

Device Name: Cool-tip™ RF Ablation System

Indications For Use:

"The Cool-tip™ RF Ablation System (Generator and Accessories) is intended for use in percutaneous, laparoscopic and intraoperative coagulation and ablation of tissue, such as partial or complete ablation of non-resectable liver lesions."

Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

PLEASE DO NOT WRITE BELOW THIS LINE
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042216