DEC 0 4 2008

K082962

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Section 5 – 510(k) Summary

Submitter:	TivaMed, Inc. 450 Sheridan Ave. Palo, Alto, CA 94306 Office: 650-321-3332 Fax: 650-326-0114
Contact Person:	Shelley Trimm RA & QS Consultant, Alquest, Inc. 4410 El Camino Real, Ste 204 Los Altos, Ca 94022 Ph: 707.508.5527 FAX: 650.559.1985 Email: strimm@alquest.com
Date Prepared:	October 2, 2008
Trade Name:	TivaMed Cooled RF System (Electrosurgical Unit and Accessories – Common Name)
Classification:	Class II 21 CFR 878.4400: Device, Electrosurgical, Cutting and Coagulation and Accessories
Product Code:	GEI
Predicate Device(s):	The subject device is equivalent to the following devices: Thermage ThermaCool™ System, K000944 (cleared 7/19/2000); and Thermage ThermaCool™ System K013639 (cleared 1/29/2002).
Device Description:	TivaMed Cooled RF System uses radiofrequency (RF) energy to selectively heat a given volume of tissue beneath the surface, while cryogen is delivered to the inside of the treatment tip to cool and protect the surface tissue.
Intended Use:	The TivaMed Cooled RF System is indicated for use in general surgical procedures for electrocoagulation and hemostasis.

Functional and Safety Testing:	To verify the device design met its functional and performance requirements, representative samples of the device underwent biocompatibility, electrical, and mechanical testing in accordance with IEC 60601-1, Medical Electrical Equipment - General Requirements for Safety; IEC 60601-1-2, IEC 60601-1-4, Medical Electrical Equipment - General Requirements for Safety – Programmable Electrical Medical Systems; IEC 60601-2-2 Medical Electrical Equipment – Particular Requirements for the Safety of High Frequency Surgical Equipment; AAMI/ANSI/ISO 11135-1:2007 Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices; ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing; Federal Register, Volume 43, No. 122, 1978; FDA "ETO, ECH, and EG Proposed Maximum Residue Limits and Maximum Limits of Exposure".
Conclusion:	TivaMed, Inc., considers the TivaMed Cooled RF System to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 4 2008

TivaMed, Inc.
% Ms. Shelley Trimm
Alquest, Inc.
4410 El Camino Real, Suite 204
Los Altos, California 94022

Re: K082962
Trade/Device Name: TivaMed Cooled RF System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 2, 2008
Received: October 3, 2008

Dear Ms. Trimm:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082962

Section 4 – Indications for Use Statement

Device Name: TivaMed Cooled RF System

The TivaMed Cooled RF System is indicated for use in general surgical procedures for electrocoagulation and hemostasis.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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