

FEB - 4 2004

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**14.0 510(k) Safety Summary**

**A. Name of Device**

Trade Name: Thermage ThermaCool System  
Common Name: Electrosurgical Unit and Accessories  
Classification Name: Device, Electrosurgical Cutting and Coagulation and Accessories (21 CFR 878.4400)  
Contact Person: Pamela M. Buckman, RN, MS  
Vice President of Regulatory/Clinical Affairs

**B. Predicate Devices**

ThermaCool TC System:

Device	Premarket Notification
ThermaCool TC System (Model TC)	K021402, Cleared 11/5/02
ThermaCool TC System (Model TC)	K013639, Cleared 1/29/02
Thermage ThermaCool IIA System	K013034, Cleared 10/4/01
Thermage ThermaCool II System	K003183, Cleared 12/8/00
Thermage ThermaCool System	K000944, Cleared 7/19/00

Other ThermaCool System Accessories that are the subject of this 510(k) include:

Accessory	Predicate	Premarket Notification
Coupling Fluid	ThermaCool Coupling Fluid TF-2	K030142, Cleared 2/3/03

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**C. Device Description**

The Thermage ThermaCool System consists of the following components:

- ThermaCool System
- Handpiece Assembly (consisting of Handpiece and Treatment Tip)
- Accessories: Coolant Canister, Coupling Fluid, Return Pad and Skin Marking Paper
- Accessory cables and tubing
- Optional footswitch component

**D. Indicated Use**

The Thermage ThermaCool System is indicated for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis. Non-invasive treatment of periorbital wrinkles and rhytids.

**E. Technical characteristics**

The technological characteristics of the Thermage ThermaCool System are substantially equivalent to those of the Thermage ThermaCool TC System, ThermaCool IIA System, ThermaCool II System, and ThermaCool System.

**F. Summary**

By virtue of design, principle of operation, materials and intended use, the Thermage ThermaCool System is substantially equivalent to devices currently cleared for marketing in the United States.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB - 4 2004

Ms. Pamela M. Buckman, RN, MS  
Vice President of Regulatory/Clinical Affairs  
Thermage, Inc.  
4058 Point Eden Way  
Hayward, California 94545-3721

Re: K033942

Trade/Device Name: Thermage ThermoCool System and Coupling Fluid  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II  
Product Code: GEI  
Dated: December 18, 2003  
Received: December 19, 2003

Dear Ms. Buckman:

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.

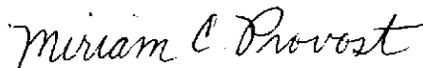
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4659. 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,

  
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): *K033942*

DEVICE NAME: Thermage ThermaCool System and Coupling Fluid

INDICATIONS FOR USE:

The Thermage ThermaCool System is indicated for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.

Non-invasive treatment of periorbital wrinkles and rhytids.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Miriam C. Provost*

Director (ODE)  
Office of General, Restorative  
and Neurological Devices

*K033942*