K052778

14.0 510(k) Safety Summary

OCT 20 2005

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

The predicate device for the ThermaCool Skin Marking Paper that is the subject of this 510(k) is:

Accessory	Predicate	Premarket Notification
Skin Marking Paper	ThermaCool Skin Marking Paper	K032088, Cleared 8/01/03

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

K033777

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. Non-invasive treatment of facial wrinkles and rhytids.

E. Technical characteristics

The technological characteristics of the Thermage ThermaCool Skin Marking Paper are substantially equivalent to those of the predicate device.

F. Summary

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2005

Pamela M. Buckman, RN, MS
Vice President of Regulatory/Clinical Affairs
Thermage, Inc.
25881 Industrial Boulevard
Hayward, California 94545-2991

Re: K052778
Trade/Device Name: Thermage ThermaCool™ System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 30, 2005
Received: October 3, 2005

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 (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/industry/support/index.html

Sincerely yours,

Barbara Buckman
for

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

Enclosure

510(k) NUMBER (IF KNOWN): Not Known K052778

DEVICE NAME: Thermage ThermaCool™ System

INDICATIONS FOR USE:

The Thermage ThermaCool System is indicated for use in:

- Dermatologic and general surgical procedures for electro coagulation and hemostasis,
- Non-invasive treatment of periorbital wrinkles and rhytids
- Non-invasive treatment of facial wrinkles and rhytids

Prescription Use	X	OR	Over-The-Counter-Use	

(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Burns

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

510(k) Number K052778