K090580

510(k) Safety Summary

JUN 26 2009

A. Name of Device

Trade Name:	Thermage ThermaCool NXT System (TG-2B)
Common Name:	Electrosurgical Unit and Accessories
Classification Name:	-Device, Electrosurgical Cutting and Coagulation and Accessories (Product Code: GEI)
	-Massager, therapeutic, electric (Product Code: ISA)
Contact Person:	Heather MacFalls Managing Director, Regulatory, Clinical and Quality

B. Predicate Devices

Device	510(k) Notification Number
Thermage ThermaCool NXT System	K033942, K032088, K031046, K043402, K051710, K052778, K072849
Syneron Medical Velasmooth Shaper	K050397, K070092, K071872
Alma Uniform Massager Handpiece/Module	K082622
Cynosure Triactive Therapeutic Massage System	K030876
LPG Therapeutic Massager/Vibrator	K990445

C. Device Description

The Thermage ThermaCool NXT System delivers capacitively coupled radiofrequency energy while cooling tissue by conduction. Components and accessories include the Multiplex (16.0) Handpiece, Standard Handpiece, Treatment Tips, Return Pad, Electronic Footswich (optional), Cryogen Canister and Coupling fluid. The front panel of the ThermaCool NXT System is equipped with a receptacle to connect the Return Pad to each Handpiece Assembly, comprising the return path for electric current. The modified Standard Handpiece offers user-selectable vibration to provide concurrent mechanical manipulation of tissue in a manner similar to the predicate devices listed.

D. Indicated Use

The radiofrequency-energy only delivery components of the Thermage ThermaCool NXT System and Accessories are indicated for use in:

- Dermatologic and general surgical procedures for electrocoagulation and hemostasis;
- Non-invasive treatment of periorbital wrinkles and rhytids including upper and lower eyelids;
- Non-invasive treatment of wrinkles and rhytids.

The simultaneous application of radiofrequency energy and skin vibration by the Thermage ThermaCool NXT System and Accessories 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 wrinkles and rhytids;
- Temporary improvement in the appearance of cellulite;
- Relief of minor muscle aches and pains;
- Relief of muscle spasms;
- Temporary improvement of local circulation (i.e., blood circulation).

E. Technical characteristics

The technological characteristics of the Thermage ThermaCool NXT System and Accessories (TG-2B), components and accessories are substantially equivalent to those of the predicate Thermage ThermaCool NXT System and Accessories.

F. Summary

By virtue of design, principle of operation, materials and intended use, the Thermage ThermaCool NXT System and Accessories 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

JUN 26 2009

Solta Medical, Incorporated
% Ms. Heather MacFalls,
Managing Director of Regulatory and Clinical Affairs
25881 Industrial Blvd.
Hayward, California 94545

Re: K090580
Trade/Device Name: Thermage Thermacool NXT System (TG-2B)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: II
Product Code: GEI, ISA
Dated: May 15, 2009
Received: May 20, 2009

Dear Ms. MacFalls:

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 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.

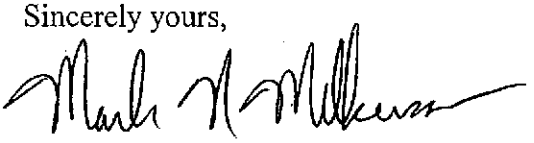
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) NUMBER (IF KNOWN):

DEVICE NAME: Thermage ThermaCool NXT System (TG-2B)

INDICATIONS FOR USE:

The radiofrequency-energy only delivery components of the Thermage ThermaCool NXT System and Accessories are indicated for use in:

- Dermatologic and general surgical procedures for electrocoagulation and hemostasis;
- Non-invasive treatment of periorbital wrinkles and rhytids including upper and lower eyelids;
- Non-invasive treatment of wrinkles and rhytids.

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- Non-invasive treatment of periorbital wrinkles and rhytids;
- Non-invasive treatment of wrinkles and rhytids;
- Temporary improvement in the appearance of cellulite;
- Relief of minor muscle aches and pains;
- Relief of muscle spasms;
- Temporary improvement of local circulation (i.e., blood circulation).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090580