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K061001

Summary of 510(k) Information *Premarket Notification, Section 510(k)*	THERMAGE, INC. OCTOBER 6, 2006

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. *Device Name:*

Trade Name: **TherMassager**

Common Name(s): Therapeutic massager

OCT 12 2006

Classification Name(s): Therapeutic massager

2. *Establishment Name & Registration Number:*

Name: Thermage, Inc,
Number: 2954746

3. *Classification(s):*

Sec. § 890.5660
(a) ***Identification.*** A therapeutic massager is an electrically powered device intended for medical purposes, such as to relieve minor muscle aches and pains.

Device Class: Class I for all requested indications
Classification Panel: Physical Medicine
Product Code(s): ISA

4. *Equivalent Predicate Device:*

Thermage believes that the TherMassager is substantially equivalent to the massage system identified below:

1. LPG Therapeutic Massager, K990445, LPG, USA, Inc.

5. *Device Description:*

The TherMassager is a self-contained, 9.0 VDC electrically powered therapeutic massager. The basic configuration is that of an ergonomically rounded hand-held box-like unit. Weight is approximately 4 pounds. The housing is made from medical grade plastic and contains a suction pump, a massage motor and skin rollers. The outside of the unit is affixed with a strap which may be secured over the operators hand to provide additional grip during treatment application. Three treatment rollers are supplied with each unit. The TherMassager unit has 1 spiral roller, 1 ribbed roller and 1 lobed (contoured) roller. The rollers are made from medical grade silicone elastomer meeting ISO 10993 biocompatibility standards.

Table of device characteristics.

Feature	TherMassager	LPG	SE?
Indications for Use	Relief of minor muscle aches and pains Relief of muscle spasm Temporary improvement of local circulation (i.e., blood circulation) Temporary improvement in the appearance of cellulite	SAME	YES
Power Requirements	AC/DC Adaptor Input = 120 VDC – 60 Hz Output = 9 VDC	120 VAC – 60 Hz	YES
Weight: **Massager** **AC/DC Adapter**	1.8 Kg .5 Kg	2 Kg – Handpiece only	YES
Leakage Current	<50 micamp	<50 micamp	YES
Vacuum (Torr) **760 Torr =** **1 atmosphere)**	Variable, 760-400 Torr	Variable, 50-500 mBar 720 – 385 Torr equivlaent	YES
Materials	Housing: medical grade plastic - 2401 MT SG Rollers: silicone – ISO 10993 compliant	Medical grade materials unspecified	YES
Massage Unit	Variable speed – User controlled	Variable according to vacuum freq. and cycle rate	YES
Vacuum frequency & cycle rate	Constant – force variable	Variable - pulsates	YES
Rollers	Powered	Powered	YES

Summary basis for equivalence.
Based on a direct comparison of the information and attributes summarized in the table above, Thermage believes that the TherMassager is substantially equivalent to the referenced massage system. Equivalence can be seen in the design, material composition, mode of action and intended use.

Indications for Use.
- Relief of minor muscle aches and pains
- Relief of muscle spasm
- Temporary improvement of local circulation (i.e., blood circulation)
- Temporary improvement in the appearance of cellulite

6. *Applicant Name & Address:*

Thermage, Inc.
25881 Industrial Blvd
Hayward, CA 94545-2991
510.782.2286 fax 510.782.2287

7. *Company Contact:*

Ms. Pamela M. Buckman, RN, MS
Thermage, Inc.
25881 Industrial Blvd
Hayward, CA 94545-2991
510.782.2286 fax 510.782.2287

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2008

Thermage, Inc.
% Ms. Sharon Thompson, VP RA/QA
25881 Industrial Boulevard
Hayward, California 94545-2991

Re: K061001
Trade/Device Name: Thermage TherMassager
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 08, 2006
Received: September 11, 2006

Dear Ms. Thompson:

This letter corrects our substantially equivalent letter of October 12, 2006.

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

Enclosure

510(k) Number: K061001

Device Name(s): *TherMassager*

Indications for Use:

The TherMassager is indicated for use in:

- Relief of minor muscle aches and pains
- Relief of muscle spasm
- Temporary improvement of local circulation "(i.e., "blood" circulation)"
- Temporary improvement in the appearance of cellulite

Prescription Use ___X___ OR Over-The-Counter Use _____

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K061001

(Per 21 CFR 801.109) (Optional format 1-2-96)