510(k) SUMMARY

Thermage CPT® System (TG-2B)

Manufacturer: Solta Medical, Inc.
25881 Industrial Blvd
Hayward, CA 94545

Contact: Raymond Lee
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SEP 0 6 2013

Date: August 2, 2013

Trade Name: Thermage CPT® System

Common Name: Electrosurgical Unit and Accessories

Classification Name: Device, Electrosurgical Cutting and Coagulation and Accessories (21 CFR 878.4400)

Product code: GEI, ISA

Device Classification: Class II

Predicate Devices: Thermage ThermaCool NXT/CPT System and Accessories
K090580

Pelleve GlideSafe™ Treatment System
K102698

Accent and Accent Family Alma Lasers
K070004, K072699, K101147

Description:

The Thermage CPT System delivers monopolar radiofrequency energy for selective coagulation of tissue while conductively cooling the epidermis. Cleared for commercial distribution under K090580, the Thermage CPT System delivers a maximum power of 500W of energy from the disposable tip to the patient.

The Handpiece delivers output energy and cooling while also offering user-selectable vibration in the vertical dimension for mechanical manipulation of tissue. Vibration is active only during each treatment cycle while the $3cm^2$ treatment tip is in contact with the skin. Vibration is not active when either the activation switch is released, when the treatment tip is not in contact with the skin, or when the $0.25cm^2$ eye tip is used.

Single-use, disposable Treatment Tips are attached to the Handpiece that comes in contact with the patient during the treatment procedure. The Treatment Tip is classified as a direct skin contact device of limited duration (<24 hours). Tips are interchangeable

to allow for treatment of a broad range of depths and surface areas. The Thermage CPT System includes the major components listed below:

Component	Description
TG-2B Console	The Thermage CPT System contains a radio frequency (RF) generator whose hardware and software control power to deliver a maximum power of 500W of energy from the disposable tip to the patient.
TH-3 Hand Piece TH-4 Hand Piece	The Handpiece and RF cable conducts the RF signal to the Thermage tip. The Handpiece also provides vibration.
Thermage Treatment Tips (sizes range from 0.25cm^2 to 16.0cm^2)	The Thermage Treatment Tips are single use, disposable tips which contact the surface of the patient's skin and delivery the RF energy through the skin.
Footswitch	Pressing the Footswitch changes the System mode from READY to ACTIVE in preparation for RF delivery.
Accessories	
Return Pad	The return pad completes the RF return path to the console
Return Pad Cable	The return pad cable connects the Return Pad to the Console
Skin Marking Grid Paper	The skin paper provides pre-defined and precise treatment zones on the applied skin area.
Coupling Fluid	The coupling fluid contributes to consistent electrical contact between the skin and the Thermage Tip and reduces friction
Cryogen	The cryogen supplies cooling effects to the skin during treatment (Cryogen is non-contact)

Device Modification:

Currently, all treatment tips (0.25cm^2, 3cm^2 and 16cm^2) are provided to the user as sterile. The change involves supplying all treatment tips to the user as "clean" and non-sterile for single patient use only.

Indications for Use:

The radiofrequency-energy only delivery components of the Thermage CPT 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 CPT System and Accessories in 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).

Substantial Equivalence Comparison:

Based on the design, component materials, function and intended use the Thermage CPT System remains substantially equivalent to devices currently marketed under the Federal Food, Drug and Cosmetic Act except for one characteristic: the condition of use of the Treatment Tips. This difference is rendered inconsequential by the "single patient use" and disposable nature of the Thermage CPT Treatment Tips that eliminates the risk of cross contamination between patients. Summarized in the tables below are the key technological characteristics and indications for use of the Thermage CPT System compared to the predicate devices listed in this Special 510(k):

Feature	Modified Thermage CPT™ System	Thermage CPT™ System	Pelleve GlideSafe™ Treatment System	Accent and Accent Family Alma Lasers	SE?
510(k)	——	K090580	K102698	K070004, K072699, K101147	-----
Classification	Class II	Class II	Class II	Class II	Yes
Energy	Radio Frequency	Radio Frequency	Radio Frequency	Radio Frequency	Yes
Frequency	6.78 MHz	6.78 MHz	4.0 MHz	40, 680 MHz	Yes
Maximum RF Power	500 Watts	500 Watts	120 Watts	300 Watts	Yes
Treatment Type	Non-Ablative	Non-Ablative	Non-Ablative	Noninvasive	Yes
Treatment Levels	Multiple Treatment Levels	Multiple Treatment Levels	Multiple Treatment Levels	Discrete Treatment Levels	Yes
HAND PIECE AND TREATMENT TIP FEATURES					
Characteristics	Hand-held handpeice	Hand-held handpeice	Hand-held handpeice	Hand-held handpeice	Yes
Electrode	Removable, exchangeable to different sizes	Removable, exchangeable to different sizes	Removable, exchangeable to different sizes	Removable, exchangeable to different sizes	Yes
Treatment Tip Condition	Non-sterile	Sterile	Non-sterile	Non-sterile	Yes
Condition of Use	Disposable Single Patient Use Only	Disposable Single Patient Use Only	Reusable Multiple Patient Use*	Reusable Multiple Patient Use*	No
Style	Monopolar/Bipolar	Monopolar/Bipolar	Monopolar/Bipolar	Unipolar/Bipolar	Yes
Treatment Tip Size	0.25 cm2 to 16cm2 surface area	0.25 cm2 to 16cm2 surface area	7.5 mm to 20 mm diameter	153.3 mm to 185	Yes

* Requires cleaning between patient uses.

	INDICATIONS FOR USE	SE?
Modified Thermage CPT™ System	- 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. - 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).	Yes
Thermage CPT™ System	- 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. - 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).	Yes
Pelleve GlideSafe™ Treatment System	Non-ablative treatment of mild to moderate facial wrinkles and rhytides for skin phototypes I-IV	Yes
Accent and Accent Family Alma Lasers	The Accent device is intended for use in dermatologic and general surgical procedures. The Accent device is indicated for use in dermatologic and general surgical procedures for the non-invasive treatment of wrinkles and rhytids using combined treatment with UniPolar and BiPolar.	Yes

HP = Hand Piece

Summary of Verification & Validation Activities:

The Special 510(k) for this device modification to the cleared Thermage CPT System (K090580) utilized the design control requirement of the Quality System Regulation (21 CFR 820). Solta Medical declares conformance to design controls in making this change and utilized the following assessments:

1. Risk documents review: FMEA's and Hazard Analysis
2. Complaints incidence and review
3. Manufacturing environment and process evaluation including bioburden monitoring trends.

Risk control measures were focused on manufacturing environment and process evaluation and providing the user with cleaning directions. No new risks remain as a result of this change.

Conclusion:

The Thermage CPT System and Accessories is substantially equivalent to devices currently marketed under the Federal Food, Drug and Cosmetic Act. The safety and effectiveness of the device modification are reasonably assured with no remaining risks justifying 510(k) clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 6, 2013

Solta Medical Incorporated
Mr. Raymond Lee
Senior Director, Regulatory Affairs
25881 Industrial Boulevard
Hayward, California 94545

Re: K132431
Trade/Device Name: Thermage CPT® System (TG-2B)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, ISA
Dated: August 2, 2013
Received: August 14, 2013

Dear Mr. Raymond Lee:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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 contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) NUMBER (IF KNOWN): K132431

DEVICE NAME: Thermage CPT® System (TG-2B)

INDICATIONS FOR USE:

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- 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).

Prescription Use__X___ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluations (ODE)

Joshua C. Nipper -S