January 8, 2018

Solta Medical Inc.
Mr. Ken Nehmer, BSEET
Director, Regulatory Affairs
351 Buena Vista Avenue E
Unit 501E
San Francisco, California 94117

Re: K173759
Trade/Device Name: Thermage CPT System and Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Additional product Code: ISA
Dated: December 7, 2017
Received: December 11, 2017

Dear Mr. Nehmer:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173759

Device Name
Thermage CPT System and Accessories

Indications for Use *(Describe)*
The radiofrequency energy 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 are 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).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

1. General Information

Submitter:

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Bothell, WA 98011
Tel: 510-259-5299

Contact Person:

Mr. Ken Nehmer, BSEET
Director, Regulatory Affairs
351 Buena Vista Avenue E, Unit 501E,
San Francisco, CA 94117
Tel: 415-297-0408
ken.nehmer@bausch.com

Revised: December 26, 2017

2. Names

Device Name	Thermage CPT System and Accessories
Classification Name	Electrosurgical Cutting and Coagulation Device and Accessories
Common Name:	Electrosurgical Unit and Accessories
CFR References:	21 CFR 878.4400
Product Codes:	GEI/ISA
Performance Standards:	No performance standards for this device have been promulgated under Section 514, Federal Food, Drug and Cosmetics Act.

3. Predicate Device

Thermage ThermaCool CPT cleared under K090580 on June 26, 2009

Thermage ThermaCool CPT cleared under K132431 on September 6, 2013

4. Product Description

The subject of this Special 510(k) submission is for the Thermage CPT System and Accessories which is substantially equivalent to the predicate Thermage CPT System and Accessories.

The Thermage CPT System delivers radio frequency energy for selective coagulation of tissue while conductively cooling the epidermis. The Thermage CPT System delivers energy from the disposable tip to the patient. The System and its Handpiece monitor skin contact

during treatment. The System employs radio frequency tuning to provide radio frequency energy across a range of impedances for delivery to the patient through single and multiple pass stamping motions of the tip.

5. Indications for Use

The radiofrequency energy 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 are 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).

6. Summary of Intended Use and Technological Characteristics

The technological characteristics of the Thermage CPT System are substantially equivalent to those of the predicate device.

Characteristic	Subject Device Thermage CPT System and Accessories	K090580 and K132431
Intended Use	Dermatologic and general surgical procedures for electrocoagulation and hemostasis, non-invasive treatment of periorbital wrinkles and rhytids.	Identical to subject device
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 radio frequency energy and skin vibration by the Thermage CPT 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).	Identical to subject device
Maximum Average Power	400W	Identical to subject device
User interface	LCD / Touchscreen Technology for user interaction and controls	Identical to subject device
Mode of Operation	Manual or Footswitch	Identical to subject device
Frequency	6.78 MHz	Identical to subject device

7. Safety and Effectiveness Information

   The review of the intended use and technical characteristics provided demonstrates the Thermage CPT System and Accessories is substantially equivalent to the predicate device.

8. Summary of the design control activities (verification/validation testing) to support the proposed changes

Risk analysis was conducted to assess the impact of modification on device and the acceptance criteria of the testing.

Summary of Testing	
Requirement	**Results**
The treatment tip design shall be capable of delivering up to the maximum REP count, and shall be verified or validated to show with 90% confidence that the tips will do so with a minimum of 90% reliability.	Pass
Latching of the Treatment Tip onto the handpiece shall be accomplished with a snap fit or latching tab.	Pass
The treatment tip design shall include a barrier against any fluid from leaking inside the tip and possibly causing an electrical short.	Pass
Treatment tips shall exhibit no external features that are sharp or that could puncture or tear nitrile gloves.	Pass
Treatment Tip design must maintain sufficient dielectric strength and integrity over the anticipated number of treatments at its highest treatment level setting in an actual or simulated use environment and include, where appropriate, applicable accessories such as Coupling Fluid, etc.	Pass
The treatment tip design shall include a tamper resistant feature that is identifiable.	Pass
Treatment tip assembly must withstand a minimum of 12 psi internal burst pressure.	Pass

9. Conclusion

   The Thermage CPT System shares the same indications for use, design features, and functional features, and thus is substantially equivalent to, the predicate device. Non-clinical test results demonstrate the Thermage CPT System is substantially equivalent to the predicate device and no new issues of safety or effectiveness have been raised.