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 22, 2017

Solta Medical, Inc.
% Ms. Melissa Thomas
Sr. Manager, Regulatory Affairs
1400 North Goodman Street
Rochester, New York 14609

Re: K170758
Trade/Device Name: Thermage FLX System
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 28, 2017
Received: August 30, 2017

Dear Ms. Thomas:

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 Industry and Consumer Education (DICE) 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) 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,

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)*
K170758

Device Name
Thermage FLX System

Indications for Use *(Describe)*
The radiofrequency-energy only delivery components of the Thermage FLX System 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 FLX 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 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1 510(k) SUMMARY

1. General Information

Submitter: Solta Medical Inc. 11720 North Creek Pkwy N., Suite 100 Bothell, WA 98011 USA General Telephone: 510-259-5299	Contact Person: Melissa Thomas 1400 North Goodman Street Rochester, NY 14609 585-338-6045 Melissa.Thomas@bausch.com

Preparation Date: February 23, 2017

2. Names

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

3. Predicate Devices

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 510(k) submission is for the Thermage FLX System which is substantially equivalent to the predicate Thermage CPT. The Thermage FLX System is based on the technology and the performance of the existing Thermage CPT System and includes a similar RF (RF) Generator and Accessories.

The Thermage FLX System delivers RF energy for selective coagulation of tissue while conductively cooling the epidermis. The Thermage FLX System delivers energy from the disposable tip to the patient. The System and its Handpiece monitor skin contact during treatment. The System employs RF tuning to provide RF energy across a range of impedances for delivery to the patient through single and multiple pass stamping motions of the tip.

The Thermage FLX System is comprised of three sub-systems: (1) the Console, (2) Handpiece and (3) Treatment Tip. Accessories used during each individual treatment included the Return Pad, Skin Marking Grid Paper, Coupling Media, Cryogen and an optional Footswitch.

5. Indications for Use

The radiofrequency (RF) energy delivery components of the Thermage FLX System 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 FLX 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 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 Technological Characteristics

The technological characteristics of the Thermage FLX System are substantially equivalent to those of the predicate devices.

Characteristic	Subject Device Thermage FLX System	K090580 and K132431
Intended Use	Dermatologic and general surgical procedures for electrocoagulation and hemostasis, non-invasive treatment of periorbital wrinkles and rhytids.	Identical as subject device
Indications for Use	The radiofrequency-energy only delivery components of the Thermage FLX System 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 FLX 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 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 as subject device
Maximum Average Power	400W	Identical as subject device
User interface	LCD / Touchscreen Technology for user interaction and controls	LCD Screen
Mode of Operation	Manual or Footswitch	Identical as subject device
Frequency	6.78 MHz	Identical as subject device

7. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Thermage FLX System is substantially equivalent to the predicate devices.

8. Brief Summary of Nonclinical Tests and Results

Safety tests of the Thermage FLX System have demonstrated its compliance with applicable requirements of the following electrical standards:

IEC 60601-1:2005 + C1(2006) + C2(2007) + AM1(2012) or IEC 60601-1:2012-Ed. 3.1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 ed3.0 (2007)/AC: 2010	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6:2010+A1:2013	Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard. Usability
IEC 60601-2-2:2009+C1:2014	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
IEC 62366-1:2015	Medical devices—Application of usability engineering to medical devices

Functional, simulated use, environmental and transport testing were also performed on representative units.

Software was verified and validated in accordance with the Solta Medical software quality procedures which comply with EN ISO 62304:2006/AC:2008 Medical device software -- Software life cycle processes.

Electromagnetic Compatibility: The console was tested to by a third party and was found to comply.

Electrical Safety: The laser console was tested to by a third party and was found to comply.

Biocompatibility: The biocompatibility evaluation of patient contacting materials was conducted per FDA draft guidance document, "Use of International Standard ISO 10993-1,

"Biological Evaluation of medical devices Part 1: Evaluation and Testing within a risk management process" dated June 16, 2016.

The Thermage FLX System passed all of the above applicable standards testing. This testing demonstrates that the functional requirements have been met and that the modified device is equivalent to the predicate devices.

9. Conclusion

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