DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 22, 2017

Cynosure, Inc.
Amy Tannenbaum
Regulatory Affairs Specialist
5 Carlisle Road
Westford, Massachusetts 01886

Re: K171262
Trade/Device Name: TempSure
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI, PBX
Dated: September 1, 2017
Received: September 5, 2017

Dear Amy Tannenbaum:

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)*
K171262

Device Name
TempSure

Indications for Use *(Describe)*
The TempSure Generator has the following indications for use:

The 10mm, 15mm, and 20mm Portrait handpieces are indicated for non-ablative treatment of mild to moderate facial wrinkles and rhytids.

The 18mm, 25mm, and 30mm Portrait handpieces provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.

The Portrait™ massage device is intended to provide a temporary reduction in the appearance of cellulite

Coagulation/Hemostasis: Using the surgical handpieces and accessories, general surgical procedures including urologic, thoracic, plastic, reconstructive, and gynecological procedures where electrosurgical coagulation of tissue is performed

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.

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"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."

Section 5	510(k) Summary

510(k) Summary for Cynosure TempSure

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) Submitter Information	
Applicant	Cynosure, Inc
Address	5 Carlisle Road, Westford MA, 01886
Phone Number	781-993-2454
Fax Number	978-256-6556
Establishment Registration Number	1222993
Contact Person	Amy Tannenbaum
Preparation Date	May 12, 2017
807.92(a)(2) Name of Device	
Trade or Proprietary Name	TempSure™ Generator
Common or Usual Name	Surgical RF Generator
Classification Name	Electrosurgical, Cutting / Coagulation / Accessories
Classification Panel	General & Plastic Surgery
Regulation	21 CFR 878.440
Regulatory Class	II
Product Code(s)	GEI, PBX
807.92 (a)(3) Legally marketed device(s) to which equivalence is claimed	
Predicate Devices	Cynosure dba Ellman Surgitron 4.0 Dual RF S5 - Pelleve (K132665) ValleyLab ForceTriad (K051644) Cynosure dba Ellman PelleFirm (K132949)
807.92(a)(4) Device Description	
	The Cynosure TempSure™ System is a radiofrequency generator with a variety of applications both aesthetic and electrosurgical procedures. The intended action is achieved through application of radiofrequency energy to the patient which results in minimization of heat dissipation and cellular alteration. Output of energy is controlled via the guided user interface (GUI) and the foot and/or hand-switch. The TempSure™ system is intended for non-ablative treatment of mild to moderate facial wrinkles and rhytids, heating for the purpose of elevating tissue temperature for selected medical conditions, and hemostasis/coagulation for general surgery applications. The generator is used with a temperature sensitive handpiece for aesthetic procedures that provides real-time temperature feedback. This temperature

	information is displayed on the user interface that shows the temperature set point and actual tissue temperature along with procedure time, system error, and warning codes. A thermistor protrudes at the end of the temperature-sensitive handpiece at the point of patient contact, which provides a constant information feedback loop as to the tissue temperature throughout a procedure. The TempSure™ System includes: • TempSure™ Surgical RF Generator • Portrait™ Temperature Sensing Handpieces • IEC Power Cord • Footswitch • Disposable/Reusable Neutral Pad • Surgical Fingerswitch/Foot Controlled Handpieces • Monopolar Cables • Disposable/Reusable Electrodes
807.92(a)(5) Intended Use of the Device	
	The TempSure Generator has the following indications for use: The 10mm, 15mm, and 20mm Portrait™ handpieces are indicated for non-ablative treatment of mild to moderate facial wrinkles and rhytids. The 18mm, 25mm, and 30mm Portrait™ handpieces provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The Portrait™ massage device is intended to provide a temporary reduction in the appearance of cellulite Coagulation/Hemostasis: Using the surgical handpieces and accessories, general surgical procedures including urologic, thoracic, plastic, reconstructive, and gynecological procedures where electrosurgical coagulation of tissue is performed
807.92(b)(1) Non-clinical tests submitted	

The following non-clinical tests have been included in this 510k submission in determination of substantial equivalence between the test device and the referenced predicates. These tests have been conducted in accordance with the FDA Guidance "Premarket Notification 510k Submissions for electrosurgical Devices for General Surgery" – Section XI. Performance Data. See Section 18 – Performance Testing, Bench. A brief summary is provided below.

Temperature Monitoring Test
The TempSure with Portrait handpieces was used at three different power settings in various treatment areas on two subjects. The FLIR Thermal Camera was used during the treatment to measure the temperature of the subjects' skin in two minute intervals over the 10 minute total treatment time. The temperature measurements of the Portrait handpieces were compared to those of the FLIR. For each treatment, the average difference in temperature between the FLIR and Portrait handpiece was +/-1.5°C. This +/- 1.5°C margin is equivalent to that of the Fluke Infrared Thermometer, which is used as the external temperature measurement tool for the device's predicates. This test proves that the TempSure with Portrait handpieces has the same temperature measurement capabilities of the Surgitron with GlideSafe or PelleFirm handpieces. In addition, this bench test proved that the TempSure with Portrait handpieces can maintain the desired temperature throughout the duration of the treatment and there were no adverse events.

Thermal Effects on Tissue Test
Testing was performed on *ex-vivo* tissue samples to compare the thermally affected zone (TAZ) of the TempSure and predicate device ForceTriad. Testing was performed using both devices in triplicate on three tissue samples (liver, kidney, and muscle), and three power settings. The depth and lateral TAZ measurements were recorded using Image-J. For each tissue and power setting combination, the TAZ created by the ForceTriad and TempSure were compared. Two of the three power bars for overlapping for each point, which shows that the TAZs were similar. This test shows that the TempSure is substantially equivalent to the ForceTriad device, despite the variation in maximum output power.

Electromagnetic Compatibility and Electrical Safety
Electrical safety testing for the Cynosure TempSure was also completed to prove the safe use of the device. These test reports are provided in accordance with FDA Guidance "Premarket Notification 510k Submissions for Electrosurgical Devices for General Surgery" – Section XII – Electrical Safety and Electromagnetic Compatibility". As per the guidance, endoscopic/laparoscopic instruments also require compliance with IEC 60601-2-18. The TempSure is not an endoscopic/laparoscopic instrument, and therefore testing to IEC 60601-2-18 is not needed. The following test reports are available in Section 17 – Electromagnetic Compatibility and Electrical Safety.

- IEC 60601-1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performances
- IEC 60601-1-2, Medical Electrical Equipment – Part 1 -2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – requirements and tests
- IEC 60601-2-2, 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

807.92(b)(2) Clinical tests submitted – N/A - No clinical tests submitted

807.92(b)(3) Conclusions drawn from clinical and non-clinical tests submitted

The nonclinical tests demonstrate that the TempSure™ electrosurgical generator safe and effective and performs as well as or better than the legally marketed predicate devices. The Temperature Monitoring test demonstrated that the temperature sensing feature worked as intended under clinical conditions at multiple temperature settings and handpiece sizes. The device was able to accurately read the temperature of the skin as similar to the Fluke used with the predicate device. It was also able to maintain the desired temperature throughout a treatment with no adverse events. The Thermal Effects on Tissue test showed that the thermally affected zone created by the TempSure™ device was similar to that created by the predicate device ForceTriad in *ex-vivo* tissue testing. Despite their difference in maximum output power, the devices created a similar TAZ and therefore the devices can be considered substantially equivalent. In addition, the Electromagnetic Compatibility and Electrical Safety testing shows that the device is safe to use and meets required standards. These non-clinical tests show that the TempSure™ generator can safely deliver RF energy to the patient as intended. The device meets design specifications as well as performance requirements.

Characteristic	Cynosure TempSure™ (K171262)	Ellman Surgitron 4.0 Dual RF S5 (Pelleve S5) (K132665)	Valley Labs Force Triad (K051644)	Ellman PelleFirm (K132949)
Indications for Use	The 10mm, 15mm, and 20mm Portrait™ handpieces are indicated for non-ablative treatment of mild to moderate facial wrinkles and rhytids The 18mm, 25mm, and 30mm Portrait™ handpieces provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The Portrait™ massage device is intended to provide a temporary reduction in the appearance of cellulite Coagulation/Hemostasis: Using the surgical handpieces and accessories, general surgical procedures including urologic, thoracic, plastic,	**Cutting:** Snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effect hemorrhage control, epistaxis treatment, turbinate shrinkage, skin incisions biopsy, cysts, abscesses, tumors, cosmetic repairs, development of skin flaps, skin tags, and blepharoplasty **Blended Cutting and Coagulation**: Snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, turbinate shrinkage, skin tags, papilloma keloids, keratosis, verrucae, basal cell carcinoma, nevi, fistulas, epithelidma, cosmetic repairs, cysts, abscesses, and development of skin tags.	**General (including urologic, thoracic, plastic and reconstructive, arthroscopic),** laparoscopic, and gynecological procedures where electrosurgical cutting and **coagulation of tissue**, and sealing (fusion) of vessels and tissue bundles is performed, including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic, cholecystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorecftomy, etc. Vessels (arteries, veins, lymph) 7mm and smaller in diameter, and bundles as large as will fit in the jaws of the devices can be sealed with Ligasure	**Tissue Heating:** The PelleFirm RF device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The PelleFirm massage device is intended to provide a temporary reduction in the appearance of cellulite.

Characteristic	Cynosure TempSure™ (K171262)	Ellman Surgitron 4.0 Dual RF S5 (Pelleve S5) (K132665)	Valley Labs Force Triad (K051644)	Ellman PelleFirm (K132949)
	reconstructive, and gynecological procedures where electrosurgical coagulation of tissue is performed	**Hemostasis**: Control of bleeding, epilation, telangiectasia. **Fulguration:** Basal cell carcinoma, papilloma, cyst destruction, tumors, verrucae, hemostasis. **Bipolar:** Pinpoint precise coagulation, pinpoint hemostasis in any field (wet or dry), snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhaging control, epistaxis treatment and turbinate shrinkage. **Wrinkles:** Non-ablative treatment of mild to moderate facial wrinkles and rhytids.	vessel sealing (tissue fusion) output.	
Rx/OTC	Prescription	Prescription	Prescription	Prescription
Energy Type	Radiofrequency	Radiofrequency	Radiofrequency	Radiofrequency
Modality	Monopolar	Monopolar, Bipolar	Monopolar, Bipolar	Monopolar, Bipolar

Section 5 510(k) Summary

Characteristic	Cynosure TempSure™ (K171262)	Ellman Surgitron 4.0 Dual RF S5 (Pelleve S5) (K132665)	Valley Labs Force Triad (K051644)	Ellman PelleFirm (K132949)
Temperature Sensing	Temperature-Sensitive Handpiece	External temperature monitor	N/A	External temperature monitor
Temperature Response Time	<1 second	N/A	N/A	N/A
Handpiece Size	10mm, 15mm, 18mm, 20mm, 25 mm, 30 mm	7.5mm, 10mm, 15mm, 20mm	N/A	25, 30 mm
Treatment Activation	Fingerswitch, Footswitch	Fingerswitch, Footswitch	Fingerswitch, Footswitch	Footswitch
Aesthetic Optimal Temperature	39-45°C	40- 45°C	N/A	40 -45°C
Patient Contacting Material	Gold-Plated Brass, Polytheramide, Loctite, Delrin	Gold-Plated Brass	Not applicable – Generator only	Delrin
Massage Head	Yes	N/A	N/A	Massage Heads, handpieces;
Output Waveform	4.0 MHz Sin-wave CW, Fully, Rectified, Partially Rectified	4.0 MHz Sin-wave CW, Fully, Rectified, Partially Rectified, and 1.7 MHz for Fulgurating Spark-Gap	472 KHz Sin-Wave CW, Fully Rectified, Partially Rectified,	4.0 MHz Sin-wave CW, Fully, Rectified, Partially Rectified, and 1.7 MHz for Fulgurating Spark-Gap (Used with Surgitron)
Maximum Frequency	4 MHz	4 MHz (Cut and Coag)	Hemo: 800 Hz Coag: 940 Hz	4 MHz

Characteristic	**Cynosure TempSure™ (K171262)**	**Ellman Surgitron 4.0 Dual RF S5 (Pelleve S5) (K132665)**	**Valley Labs Force Triad (K051644)**	**Ellman PelleFirm (K132949)**
Modes	Coag, Portrait	Cut, Blend, Coag, Fulgurate, Bipolar	Cut, Valleylab, Coag, Bipolar, Autobipolar, Ligasure	Cut, Blend, Coag, Fulgurate, Bipolar
Max Power Output	50W (Coag) 120W (wrinkle) 300W (tissue heating)	120W	200W	120W
Dimensions	18” x 18” x 12”	9.5” x 7.1” x 16.1”	18” x 20” x 10”	Handpiece only (approx.. 6.13” x 1.46” x 0.94”)
Weight	30 lbs	26 lbs	30 lbs	Handpiece only