October 24, 2018

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

Re: K182365
Trade/Device Name: TempSure System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 29, 2018
Received: August 30, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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
Indications for Use

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

The 25mm, and 30mm 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 massage device is intended to provide a temporary reduction in the appearance of cellulite

The following surgical modes are applicable to the generator:

Coagulation/Hemostasis: General surgical procedures including urologic, thoracic, plastic, reconstructive, and gynecological procedures where electrosurgical coagulation of tissue is performed

Cutting: snoring. submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective 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 flaps.

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 hemorrhage control. epistaxis treatment and turbinate shrinkage

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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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.”
510(k) Summary for Cynosure TempSure System

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

<table>
<thead>
<tr>
<th>Applicant</th>
<th>Cynosure, Inc</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>5 Carlisle Road, Westford MA, 01886</td>
</tr>
<tr>
<td>Phone Number</td>
<td>781-993-2454</td>
</tr>
<tr>
<td>Fax Number</td>
<td>978-256-6556</td>
</tr>
<tr>
<td>Establishment Registration Number</td>
<td>1222993</td>
</tr>
<tr>
<td>Contact Person</td>
<td>Amy Tannenbaum</td>
</tr>
<tr>
<td>Preparation Date</td>
<td>August 29, 2018</td>
</tr>
</tbody>
</table>

### 807.92(a)(2) Name of Device

<table>
<thead>
<tr>
<th>Trade or Proprietary Name</th>
<th>TempSure System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common or Usual Name</td>
<td>Surgical RF Generator</td>
</tr>
<tr>
<td>Classification Name</td>
<td>Electrosurgical, Cutting / Coagulation / Accessories</td>
</tr>
<tr>
<td>Classification Panel</td>
<td>General &amp; Plastic Surgery</td>
</tr>
<tr>
<td>Regulation</td>
<td>21 CFR 878.4400</td>
</tr>
<tr>
<td>Regulatory Class</td>
<td>II</td>
</tr>
<tr>
<td>Product Code(s)</td>
<td>GEI, PBX</td>
</tr>
</tbody>
</table>

### 807.92(a)(3) Legally marketed device(s) to which equivalence is claimed

<table>
<thead>
<tr>
<th>Predicate Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cynosure TempSure (K171262)</td>
</tr>
<tr>
<td>Cynosure dba Ellman Surgitron 4.0 Dual RF S5 - Pelleve (K123366)</td>
</tr>
<tr>
<td>ValleyLab ForceTriad (K051644)</td>
</tr>
</tbody>
</table>

### 807.92(a)(4) Device Description

The Cynosure TempSure™ System is a radiofrequency generator with a variety of applications both aesthetic and surgical 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 generator has been upgraded to include additional surgical modes – Cut, Bipolar, Fulgurate, and Blend, along with the existing Coag. The power of the device for Surgical applications is a maximum of 300W. There have been no changes to the Smart Handpiece treatment with temperature sensitive handpieces. The
TempSure system is used with the same existing Ellman electrosurgical accessories.

The TempSure™ System includes:
- TempSure™ Generator
- Temperature Sensing Handpieces
- IEC Power Cord
- Footswitch
- Disposable/Reusable Neutral Pad
- Surgical Fingerswitch/Foot Controlled Handpieces
- Monopolar Cables
- Disposable/Reusable Electrodes, Forceps

### 807.92(a)(5) Intended Use of the Device

The TempSure System has the following indications for use:

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

The 25mm, and 30mm 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 massage device is intended to provide a temporary reduction in the appearance of cellulite.

The following surgical modes are applicable to the generator:

**Coagulation/Hemostasis:** General surgical procedures including urologic, thoracic, plastic, reconstructive, and gynecological procedures where electrosurgical coagulation of tissue is performed.

**Cutting:** snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective 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 flaps.

**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 hemorrhage
control. epistaxis treatment and turbinate shrinkage

### 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. E – System Testing,
Thermal Effects on Tissue. See Section 18 - Performance Testing, Bench. A brief summary is provided
below.

**Thermal Effects on Tissue**
Testing was performed on *ex-vivo* tissue samples to compare the thermally affected zone (TAZ) of the
TempSure and predicate devices. Measurements were taken in triplicate on three tissue samples (liver,
kidney, and muscle), and three power settings. For each tissue and power setting combination, the
TempSure and the predicate device(s) were compared. This test shows that the TempSure is
substantially equivalent to the ForceTriad and Surgitron devices.

**Electromagnetic Compatibility and Electrical Safety**
Electrical safety testing for the Cynosure TempSure System 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”. 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™ system is safe and effective and performs as well as the legally marketed predicate devices. 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 devices, Surgitron and 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. The non-clinical testing shows that the device meets design specifications as well as performance requirements.
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Cynosure TempSure™ (KPending)</th>
<th>Cynosure TempSure (K171262)</th>
<th>Ellman Surgitron 4.0 Dual RF S5 (Pelleve S5) (K123366)</th>
<th>Valley Labs Force Triad (K051644)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications for Use</strong></td>
<td>The 10mm, 15mm, and 20mm Smart handpieces are indicated for non-ablative treatment of mild to moderate facial wrinkles and rhytids. The 25mm, and 30mm Smart 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 massage device is intended to provide a temporary reduction in the appearance of cellulite. The following surgical modes are applicable to the generator: <strong>Coagulation/Hemostasis:</strong> General surgical procedures including urologic, thoracic, plastic, reconstructive, and gynecological procedures.</td>
<td>The 10mm, 15mm, and 20mm handpieces are indicated for non-ablative treatment of mild to moderate facial wrinkles and rhytids. The 18mm, 25mm, and 30mm 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 massage device is intended to provide a temporary reduction in the appearance of cellulite. <strong>Coagulation/Hemostasis:</strong> Using the surgical handpieces and accessories, general surgical procedures including urologic, thoracic, plastic, reconstructive, and gynecological procedures where electrosurgical</td>
<td><strong>Cutting:</strong> Snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, turbinate shrinkage, skin incisions biopsy, cysts, abscesses, tumors, cosmetic repairs, development of skin flaps, skin tags, and blepharoplasty. <strong>Blended Cutting and Coagulation:</strong> 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</td>
<td>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, oophorectomy, etc. Vessels (arteries, veins, lymph) 7mm and smaller in diameter, and bundles as large as will fit in</td>
</tr>
</tbody>
</table>

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<tr>
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<th>Valley Labs Force Triad (K051644)</th>
</tr>
</thead>
<tbody>
<tr>
<td>where electrosurgical coagulation of tissue is performed</td>
<td>coagulation of tissue is performed</td>
<td>development of skin tags.</td>
<td>the jaws of the devices can be sealed with Ligasure vessel sealing (tissue fusion) output.</td>
<td></td>
</tr>
</tbody>
</table>

**Cutting:** snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective 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.

**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.
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Cynosure TempSure™ (KPending)</th>
<th>Cynosure TempSure (K171262)</th>
<th>Ellman Surgitron 4.0 Dual RF S5 (Pelleve S5) (K123366)</th>
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</tr>
</thead>
</table>
| cosmetic repairs, cysts, abscesses, and development of skin flaps.  
**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 hemorrhage control, epistaxis treatment and turbinate shrinkage |
<p>| Rx/OTC | Prescription | Prescription | Prescription | Prescription |
| Energy Type | Radiofrequency | Radiofrequency | Radiofrequency | Radiofrequency |
| Modality | Monopolar, Bipolar | Monopolar | Monopolar, Bipolar | Monopolar, Bipolar |
| Temperature Sensing | Temperature-Sensitive Handpiece | Temperature-Sensitive Handpiece | External temperature monitor | N/A |
| Temperature Response Time | &lt;1 second | &lt;1 second | N/A | N/A |
| Handpiece Size | 10mm, 15mm, 20mm, 25 mm, 30 mm | 10mm, 15mm, 18mm, 20mm, 25 mm, 30 mm | 7.5mm, 10mm, 15mm, 20mm | N/A |
| Treatment Activation | Fingerswitch, Footswitch | Fingerswitch, Footswitch | Fingerswitch, Footswitch | Fingerswitch, Footswitch |</p>
<table>
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<th>Cynosure TempSure™ (KPending)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Aesthetic Optimal Temperature</td>
<td>39-45°C</td>
<td>39-45°C</td>
<td>40-45°C</td>
<td>N/A</td>
</tr>
<tr>
<td>Patient Contacting Material</td>
<td>Gold-Plated Brass, Polytheramide, Loctite, Delrin</td>
<td>Gold-Plated Brass, Polytheramide, Loctite, Delrin</td>
<td>Gold-Plated Brass</td>
<td>Not applicable – Generator only</td>
</tr>
<tr>
<td>Massage Head</td>
<td>Yes</td>
<td>Yes</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Output Waveform</td>
<td>4.0 MHz Sin-wave CW, Fully Rectified, Partially Rectified, and 1.7 MHz for Bipolar</td>
<td>4.0 MHz Sin-wave CW</td>
<td>4.0 MHz Sin-wave CW, Fully Rectified, Partially Rectified, Modulation and 1.7 MHz for Bipolar</td>
<td>472 KHz Sin-Wave CW, Fully Rectified, Partially Rectified,</td>
</tr>
<tr>
<td>Modes</td>
<td>Surgical (Coag, Cut, Blend, Fulgurate, Bipolar) Smart Handpiece Mode</td>
<td>Surgical Mode (Coag only), Portrait Mode (Smart Handpiece)</td>
<td>Cut, Blend, Coag, Fulgurate, Bipolar</td>
<td>Cut, Valleylab, Coag, Bipolar, Autobipolar, Ligasure</td>
</tr>
<tr>
<td>Max Power Output</td>
<td>300W (Surgical)</td>
<td>50W (Surgical – Coag only)</td>
<td>120W</td>
<td>300W</td>
</tr>
<tr>
<td></td>
<td>120W (Wrinkles)</td>
<td>120W (Wrinkles)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>300W (Tissue Heating)</td>
<td>300W (Tissue Heating)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dimensions</td>
<td>22.5” x 18” x 12”</td>
<td>18” x 18” x 12”</td>
<td>9.5” x 7.1” x 16.1”</td>
<td>18” x 20” x 10”</td>
</tr>
<tr>
<td>Weight</td>
<td>30 lbs</td>
<td>30 lbs</td>
<td>26 lbs</td>
<td>30 lbs</td>
</tr>
</tbody>
</table>