



July 24, 2019

Cynosure, Inc  
Michael King  
Regulatory Affairs Specialist II  
5 Carlisle Road  
Westford, Massachusetts 01886

Re: K190678

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, PBX  
Dated: March 15, 2019  
Received: March 18, 2019

Dear Michael King:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.  
Assistant Director  
DHT4A: Division of General Surgery Devices  
OHT4: Office of Surgical  
and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K190678

Device Name

TempSure System

Indications for Use (Describe)

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

The 18mm, 25mm, 30mm, and 60mm 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.**

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### 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.

<b>807.92(a)(1) Submitter Information</b>	
Applicant	Cynosure, LLC
Address	5 Carlisle Road, Westford MA, 01886
Phone Number	781-993-2454
Fax Number	978-256-6556
Establishment Registration Number	1222993
Contact Person	Michael King
Preparation Date	March 15, 2019
<b>807.92(a)(2) Name of Device</b>	
Trade or Proprietary Name	TempSure System
Common or Usual Name	Surgical RF Generator
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories; Massager, Vacuum, Radio Frequency Induced Heat
Classification Panel	General & Plastic Surgery
Regulation	21 CFR 878.4440
Regulatory Class	II
Product Code(s)	GEI, PBX
<b>807.92 (a)(3) Legally marketed device(s) to which equivalence is claimed</b>	
Predicate Devices	Cynosure TempSure (K182365) Cynosure TempSure (K171262)

**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.

An additional 60mm Smart Handpiece is now included for the purpose of tissue heating for selected medical conditions. The 60mm handpiece can also be used with a new massage head for the temporary reduction in the appearance of cellulite. The handpiece has the same maximum output power of 300W in the Smart Handpiece Mode. In addition, a new larger disposable neutral pad is provided for these body treatments. There have been no additional changes to the previous existing handpieces (10, 15, 18, 20, 25, or 30mm) or Surgical modes (COAG, Cut, Blend, Bipolar, Fulgurate) of the system. The TempSure system is still used with the same existing electro-surgical accessories.

The TempSure™ System includes:

- TempSure™ Generator
- Temperature Sensing Handpieces (10, 15, 18, 20, 25, 30, and 60mm)
- Massage Heads (25, 30, and 60mm)
- IEC Power Cord
- Footswitch
- Disposable/Reusable Neutral Pads
- Surgical Fingerswitch/Foot Controlled Handpieces
- Monopolar Cables
- Disposable/Reusable Electrodes, Forceps

New Additions to the TempSure System include:

- 60mm Smart Handpiece (ASY-12745)
- 60mm Massage Head (ASY-12746)
- Large Neutral Pad (MEL-01197)

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

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

The 18mm, 25mm, 30mm, and 60mm 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.

**Tissue Heating with 60mm Handpiece**

Bench testing was conducted to show that the new 60mm handpiece and large neutral pad, when used in a simulated clinical condition, was able to heat and maintain temperature of the treatment area for 10 minutes. Refer to Section 18 – Performance Testing, Bench for additional information.

**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”. 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 non-clinical tests demonstrate that the TempSure generator with the 60mm handpiece is safe and effective and performs as well or better than the legally marketed predicate device. The Tissue Heating bench test demonstrated that the device is able to maintain temperature for at least the 10-minute treatment time when used as intended under clinical conditions at various treatment areas and settings. In addition, the Electrosurgical 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 using the 60mm handpiece meets design specifications as well as performance requirements.



Characteristic	Cynosure TempSure System (K190678)	Cynosure TempSure System (K182365)	Cynosure TempSure (K171262)
<b>Indications for Use</b>	<p>The 10mm, 15mm, and 20mm handpieces are indicated for non-ablative treatment of mild to moderate facial wrinkles and rhytids.</p> <p>The 18mm, 25mm, 30mm, and 60mm 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.</p> <p>The massage device is intended to provide a temporary reduction in the appearance of cellulite</p> <p>The following surgical modes are applicable to the generator:</p> <p><b>Coagulation/Hemostasis:</b> General surgical procedures including urologic, thoracic, plastic, reconstructive, and gynecological procedures where electrosurgical coagulation of tissue is performed</p> <p><b>Cutting:</b> snoring. submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP),</p>	<p>The 10mm, 15mm, and 20mm handpieces are indicated for non-ablative treatment of mild to moderate facial wrinkles and rhytids</p> <p>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.</p> <p>The massage device is intended to provide a temporary reduction in the appearance of cellulite</p> <p>The following surgical modes are applicable to the generator:</p> <p><b>Coagulation/Hemostasis:</b> General surgical procedures including urologic, thoracic, plastic, reconstructive, and gynecological procedures where electrosurgical coagulation of tissue is performed</p> <p><b>Cutting:</b> snoring. submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control. epistaxis treatment, turbinate shrinkage. skin incisions, biopsy, cysts, abscesses. tumors.</p>	<p>The 10mm, 15mm, and 20mm handpieces are indicated for non-ablative treatment of mild to moderate facial wrinkles and rhytids</p> <p>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.</p> <p>The massage device is intended to provide a temporary reduction in the appearance of cellulite</p> <p><b>Coagulation/Hemostasis:</b> Using the surgical handpieces and accessories, general surgical procedures including urologic, thoracic, plastic, reconstructive, and gynecological procedures where electrosurgical coagulation of tissue is performed</p>

	<p>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.</p> <p><b>Blended Cutting and Coagulation:</b> 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.</p> <p><b>Fulguration:</b> basal cell carcinoma. papilloma. cyst destruction, tumors. verrucae, hemostasis.</p> <p><b>Bipolar:</b> 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>	<p>cosmetic repairs, development of skin flaps. skin tags and blepharoplasty.</p> <p><b>Blended Cutting and Coagulation:</b> 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.</p> <p><b>Fulguration:</b> basal cell carcinoma. papilloma. cyst destruction, tumors. verrucae, hemostasis.</p> <p><b>Bipolar:</b> 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>	
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Characteristic	Cynosure TempSure System (K190678)	Cynosure TempSure System (K182365)	Cynosure TempSure (K171262)
Rx/OTC	Prescription	Prescription	Prescription
Energy Type	Radiofrequency	Radiofrequency	Radiofrequency
Modality	Monopolar, Bipolar	Monopolar, Bipolar	Monopolar
Temperature Sensing	Temperature-Sensitive Handpiece	Temperature-Sensitive Handpiece	Temperature-Sensitive Handpiece
Temperature Response Time	<1 second	<1 second	<1 second
Handpiece Size	10mm, 15mm, 18mm, 20mm, 25 mm, 30 mm, 60mm	10mm, 15mm, 20mm, 25 mm, 30 mm	10mm, 15mm, 18mm, 20mm, 25 mm, 30 mm
Treatment Activation	Fingerswitch, Footswitch	Fingerswitch, Footswitch	Fingerswitch, Footswitch
Aesthetic Optimal Temperature	39-45°C	39-45°C	39-45°C
Patient Contacting Material	Gold-Plated Aluminum, PVDF, Polyetherimide, Loctite, Delrin, Polycarbonate sabic lexan, Hydrogel	Gold-Plated Brass, Polyetherimide, Loctite, Delrin	Gold-Plated Brass, Polyetherimide, Loctite, Delrin
Massage Head	Yes	Yes	Yes
Output Waveform	4.0 MHz Sin-wave CW, Fully Rectified, Partially Rectified, and 1.7 MHz for Bipolar	4.0 MHz Sin-wave CW, Fully Rectified, Partially Rectified, and 1.7 MHz for Bipolar	4.0 MHz Sin-wave CW
Modes	Surgical (Coag, Cut, Blend, Fulgurate, Bipolar) Smart Handpiece Mode	Surgical (Coag, Cut, Blend, Fulgurate, Bipolar) Smart Handpiece Mode	Surgical (Coag only) Portrait Mode (Smart Handpiece)
Max Power Output	300W (Surgical) 120W (Wrinkles) 300W (Tissue Heating)	300W (Surgical) 120W (Wrinkles) 300W (Tissue Heating)	50W (Surgical – Coag only) 120W (Wrinkles) 300W (Tissue Heating)
Dimensions	22.5” x 18” x 12”	22.5” x 18” x 12”	18” x 18” x 12”
Weight	30 lbs	30 lbs	30 lbs