March 18, 2022

Cynosure, LLC
Michael King
Regulatory Affairs Specialist III
5 Carlisle Road
Westford, Massachusetts 01886

Re: K212891
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: February 17, 2022
Received: February 18, 2022

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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
~~Pending~~ K212891

Device Name
TempSure System

Indications for Use *(Describe)*
The Small 10mm, 10mm, 15mm, and 20mm handpieces are indicated for non-ablative treatment of mild to moderate facial wrinkles and rhytids.

The Small 10mm, 18mm, 25mm, 30mm, and 60mm handpieces and the FlexSure Applicators 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.

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."

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, 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	September 9, 2021
807.92(a)(2) Name of Device	
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
807.92 (a)(3) Legally marketed device(s) to which equivalence is claimed	
Predicate Devices	Cynosure TempSure (K200241)
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 Small 10mm Smart Handpiece is now included for the purpose of tissue heating for selected medical conditions and the treatment of mild to moderate facial wrinkles and rhytids. The handpiece is capable of operating at maximum energy setting of 30 (28W) in the Smart Handpiece Mode. There have been no additional changes to the previous existing handpieces (10, 15, 18, 20, 25, 30 or 60mm), FlexSure Applicators, or Surgical modes (COAG, Cut, Blend,

	Bipolar, Fulgurate) of the system. The TempSure system is still used with the same existing electrosurgical accessories. The TempSure™ System includes: • TempSure™ Generator • Temperature Sensing Handpieces (Small 10, 10, 15, 18, 20, 25, 30, and 60mm) • Massage Heads (25, 30, and 60mm) • FlexSure™ Applicators (Large and Medium) • IEC Power Cord • Footswitch • Disposable/Reusable Neutral Pads • Surgical Fingerswitch/Foot Controlled Handpieces • Monopolar Cables • Disposable/Reusable Electrodes, Forceps
807.92(a)(5) Intended Use of the Device	
	The Small 10mm, 10mm, 15mm, and 20mm handpieces are indicated for non-ablative treatment of mild to moderate facial wrinkles and rhytids. The Small 10mm, 18mm, 25mm, 30mm, and 60mm handpieces and the FlexSure Applicators 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(a)(6) Summary of the Technological Characteristics of the Device Compared to the Predicate – Please refer to the System Specification Comparison Table below

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 Small 10mm Handpiece
Bench testing was conducted to show that the new Small 10mm Smart Handpiece, 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

Section 5	510(k) Summary

The non-clinical tests demonstrate that the TempSure generator with the Small 10mm 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 Small 10mm handpiece meets design specifications as well as performance requirements.

Characteristic	Cynosure TempSure System (KPending)	Cynosure TempSure System (K200241)
Indications for Use	The Small 10mm, 10mm, 15mm, and 20mm handpieces are indicated for non-ablative treatment of mild to moderate facial wrinkles and rhytids. The Small 10mm, 18mm, 25mm, 30mm, and 60mm handpieces and the FlexSure Applicators 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	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 and the FlexSure Applicators 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,

Characteristic	Cynosure TempSure System (KPending)	Cynosure TempSure System (K200241)
	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	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
Rx/OTC	Prescription	Prescription
Energy Type	Radiofrequency	Radiofrequency
Modality	Monopolar, Bipolar	Monopolar, Bipolar
Temperature Sensing	Temperature-Sensitive Handpiece	Temperature-Sensitive Handpiece
Temperature Response Time	<1 second	<1 second
Handpiece Size	Small 10mm, 10mm, 15mm, 18mm, 20mm, 25 mm, 30 mm, 60mm, Large & Medium FlexSure Applicators	10mm, 15mm, 18mm, 20mm, 25 mm, 30 mm, 60mm, Large & Medium FlexSure Applicators
Massage Head	Yes (25mm, 30mm, 60mm)	Yes (25mm, 30mm, 60mm)
Surgical Accessories	The TempSure™ generator is compatible with existing, previously cleared electrosurgical accessories: neutral pads, electrodes, surgical handpieces, cables, etc.	The TempSure™ generator is compatible with existing, previously cleared electrosurgical accessories: neutral pads, electrodes, surgical handpieces, cables, etc.
Treatment Activation	Fingerswitch, Footswitch	Fingerswitch, Footswitch

Section 5	510(k) Summary

Characteristic	Cynosure TempSure System (KPending)	Cynosure TempSure System (K200241)
Aesthetic Optimal Temperature	39-45°C	39-45°C
Patient Contacting Material	**Small 10mm Handpiece:** Gold-plated 316 stainless steel **Handpieces**: PVDF coating, Gold-plated brass, Gold-plated aluminum, Loctite (M-31CL), Polyetherimide (Ultem 1000) **FlexSure**: Polyimide, Hydrogel **Massage Heads**: Polycarbonate (Sabic Lexan HP-1), Delrin	**Handpieces**: PVDF coating, Gold-plated brass, Gold-plated aluminum, Loctite (M-31CL), Polyetherimide (Ultem 1000) **FlexSure**: Polyimide, Hydrogel **Massage Heads**: Polycarbonate (Sabic Lexan HP-1), Delrin
Input Voltage	110V	110V
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
Modes	Surgical (Coag, Cut, Blend, Fulgurate, Bipolar) Smart Handpiece Mode	Surgical (Coag, Cut, Blend, Fulgurate, Bipolar) Smart Handpiece Mode
Max Power Output	300W (Surgical) 120W (Wrinkles) 300W (Tissue Heating)	300W (Surgical) 120W (Wrinkles) 300W (Tissue Heating)
Safety Features	• Compliant with medical electrical equipment requirements for safety and performance (60601-1, 60601-1-2, 60601-2-2) • Small 10mm Smart Handpiece is equipped with an integrated accelerometer to detect handpiece motion. RF will be disabled when no handpiece motion is detected.	• Compliant with medical electrical equipment requirements for safety and performance (60601-1, 60601-1-2, 60601-2-2)
Crest Factor	3.1 (Surgical) 1.5 (Smart Handpiece)	3.1 (Surgical) 1.5 (Smart Handpiece)
Dimensions	22.5” x 18” x 12”	22.5” x 18” x 12”
Weight	30 lbs	30 lbs