November 21, 2024

General Vibronics, Inc.
Huan Truong
President
1615 East Warner Road
Suite #4
Tempe, Arizona 85284

Re: K242553
Trade/Device Name: MIRARI® Cold Plasma System (GV-M2-01)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX, GEI
Dated: October 31, 2024
Received: October 31, 2024

Dear Huan Truong:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.11.21 13:57:10 -05'00'

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)*
K242553

Device Name
MIRARI® Cold Plasma System (GV-M2-01)

Indications for Use *(Describe)*

MIRARI® Cold Plasma System provides 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.

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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510(K) Summary
Mirari Cold Plasma System
K242553

Applicant	General Vibronics
Address	1615 East Warner Road Suite #4 Tempe, AZ 85284 US
Contact Person	Mr. Huan Truong, President
Contact Information	huan@generalvibronics.com
Preparation Date	November 20, 2024
Device Trade Name	Mirari Cold Plasma System
Common Name	RF for Pain Relief
Regulation Number	878.4400
Product Code	PBX, GEI
Regulatory Class	II
Legally Marketed Predicate Device	Tempsure Flexsure Applicator (K200241

Device Description:

The Mirari Cold Plasma System is a portable, hand-held device that emits RF energy at 80kHz. The system is comprised of a battery-operated RF generator, a rechargeable power supply powered by a pair of lithium batteries and a plasma array which is placed in fleece pouch. The plasma array is then placed in a fleece pouch which is then placed on the skin and the RF energy is emitted through the array..

Indications for use:
MIRARI® Cold Plasma System provides 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.

Indication for Use Comparison

Description	Mirari	TempSure	Comparison
	(K)242553	(K)200241	
Indications for Use	The Mirari Cold Plasma System provides 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 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	Same

Technology Comparison

Technical Specification	**Subject Device: Mirari Cold Plasma Device**	**Predicate Device: TempSure FlexSure Applicator**	**Comparison**
Rx/OTC	Prescription	Prescription	Same
Energy Type	Radiofrequency	Radiofrequency	Same
Modality	Dielectric barrier discharge (DBD)	Diathermy by high voltage insulated electrode	Different
Mechanism of Action	Uses RF energy for therapeutic purposes through a resonant inverter and plasma array	Uses RF energy or other sources to create localized heating	Similar RF energy generation using RF energy, focusing on tissue heating
Heating Mechanism	RF energy heating at a resonant frequency of ~77kHz with specified frequencies	Uses RF energy for localized heating at specified frequencies	Both use RF energy for heating; subject device uses a resonant frequency for precise control

Technical Specification	Subject Device: Mirari Cold Plasma Device	Predicate Device: TempSure FlexSure Applicator	Comparison
Treatment Modalities	CAP (capacitive coupling) and RES (resistive heating) modes for different tissue types	CAP and RES modes or similar for different depths and conditions	Similar modalities, both adapting to various tissue characteristics
Plasma Array & Tip Dimensions	Interconnected metal rings, 1.6mm diameter, 0.2mm thick	Varies in design but typically includes metal elements for RF energy generation	Both involve specially designed arrays; subject device provides specific dimensions
Handpiece Size	Fleece pouch covering the array and connector, 6.5cm x 14cm x 0.7cm	Oval shape in large (398 cm^2) and medium (250 cm^2) sizes	Different
Intended Treatment Size	29 cm^2	Same as applicator size	Same
Treatment Area	Defined by plasma array design for consistent energy distribution	Defined by array or applicator design	Comparable in defining the treatment area through the array size and design
Total Power	Less than 4W	Less than 300W	Different
Maximum Output Power	Dependent on modulation duty cycle (30%), controlled by PWM	Varies for safety and effectiveness	Both control power output for safety; subject device specifies detailed control
Electric Field	Less than 80V/m	Less than 1200V/m	Different
Waveform Modulation	Uses PWM (pulse width modulation) with precise control	Uses PWM or similar techniques	Both use PWM for precise energy delivery

Technical Specification	Subject Device: Mirari Cold Plasma Device	Predicate Device: TempSure FlexSure Applicator	Comparison
Output Waveform	80 kHz Sine-wave CW, Fully Rectified	4.0 MHz Sine-wave CW, Fully Rectified, Partially Rectified, 1.7 MHz for Bipolar	Different
Temperature Response Time	<1 second	<1 second	Same
Treatment Temperature	Maintains within ±2°C of target temperature using temperature sensor and feedback algorithm.	Maintains temperature within a specified tolerance	Similar temperature management; subject device specifies ±2°C tolerance
Maximum Allowable Temperature	Adjusts power or shuts down if safe threshold is exceeded	Adjusts power or shuts down if temperature exceeds settings	Both prioritize preventing temperature-related adverse events
Temperature Monitoring	High-precision sensor polled twice per second with feedback control	Uses sensors for safe operating temperatures	Comparable focus on real-time monitoring with feedback loops
Temperature Tolerance/Accuracy	±2°C tolerance	Typically within similar tolerance ranges	Both aim for precise temperature control
Treatment Duration	Duration of treatment varies based on patient needs. 10 minutes per treatment protocol	Generally set based on clinical protocols	Similar adaptability based on patient needs
Safety Measures	Magnetic interlocks, overcurrent shutdown, adaptive control; detects array presence to prevent accidental use	Uses interlocks, power control mechanisms, automatic shutdowns	Both prioritize multiple safety layers; subject device details detection and response mechanisms

Technical Specification	Subject Device: Mirari Cold Plasma Device	Predicate Device: TempSure FlexSure Applicator	Comparison
Patient Contacting Material	Polyester fleece, 300 grams/m² double layer	Gold-Plated Aluminum, PVDF, Polyetherimide, Loctite, Delrin, Polycarbonate, Hydrogel	Different
Mirari Driver Dimensions	2.56” x 3.98” x 1.22”	22.5” x 18” x 12”	Different
Weight	1 lb	30 lbs	Different

Frequency:

The frequencies are different as the Mirari delivers energy at 80kHz and the predicate delivers energy at 4mHz. The Mirari demonstrated in the thermal testing that was conducted that it can safely elevate the tissue temperature and hold that temperature for 10 minutes, which is the therapeutic requirement for a pain relief device.

According to the Tempsure FlexSure application 510K Summary, the same testing was conducted, specifically: Bench testing was conducted to show that the new FlexSure single use applicator 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.

There is no new concern for safety or efficacy because both devices performed the same test and achieved the same result.

Applicator Size:

The applicator for the Mirari is smaller than the predicate device. There is no new concerns for safety or efficacy because both devices performed the same test and achieved the same result.

Patient Contacting Material:

The patient contacting material for the Mirari is different than the predicate device. There are no new concerns for safety or efficacy as these materials have been evaluated for biocompatibility. The materials are safe for their intended use and introduce no additional risk.

Performance Testing

Verification and validation activities were successfully completed and establish that the Mirari Cold Plasma System control unit performs as intended. Testing included the following:

- 60601-1 Edition 3.2 2020-08; Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-1-2:2014 + A1:2020; Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests;
- IEC 60601-2-2:2017; 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 62304:2006+A1:2015; Medical Device – Software Life Cycle Processes;
- EN ISO 14971:2019+A11:2021; Medical Devices – Application of Risk Management To Medical Devices

Software verification and validation testing was conducted, and documentation provided in accordance with FDA's Guidance or the Content of Premarket Submissions for Software Contained in Medical Devices.

In addition, tests were performed to demonstrate that the device can maintain a therapeutic temperature for 10 minutes of treatment for every electrode used. Tests included three subjects and a the therapeutic temperature was maintained for 10 minutes of treatment.

Performance testing was performed to demonstrate the accuracy of the output power, output frequency, and output voltage.

Conclusion

The Mirari Cold Plasma System shares similar technological characteristics, theory of operation, design, and indications with its predicate TempSure FlexSure device as described above. Despite the differences in the Mirari Cold Plasma System and the TempSure FlexSure applicator bench testing was conducted to support that the device can successfully heat the treatment area. Based on the above information and test reports, it is determined that the proposed Mirari Cold Plasma System is substantially equivalent to the predicate device and there are no new concerns raised for safety or efficacy.