April 13, 2023

TermoSalud
% Ms. Aubrey Thompson, MS
Regulatory Consultant
Hoy and Associates Regulatory Consulting
1830 Bonnie Way
Sacramento, California 95825

Re: K230412
Trade/Device Name: Symmed Elite Aesthetic
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: February 14, 2023
Received: February 15, 2023

Dear Ms. Thompson:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.04.13 10:47:10 -04'00'

Mark Trumbore, 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)*
K230412

Device Name
Symmed Elite Aesthetic

Indications for Use *(Describe)*

The Symmed Elite Aesthetic is intended to provide topical heating for the purpose of elevating tissue temperature for treatment of selected medical conditions such as: relief of pain, muscle spasms, increase in local circulation.

The massage device provided is intended to provide a temporary reduction in the appearance of cellulite.

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.

510(K) Summary
Symmed Elite Aesthetic
K230412

This 510(K) Summary of safety and effectiveness for the Symmed Elite Aesthetic is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant	Termosalud
Address	Ataulfo Friera Tarfe, 8 -33211 Gijón, Spain
Contact Person	Ms. Aubrey Thompson, MS Regulatory Consultant
Contact Information	Aubreythompson@hoyregulatory.com (323)533-8994 1830 Bonnie Way Sacramento, CA 95825
Preparation Date	April 12, 2023
Device Trade Name	Symmed Elite Aesthetic
510(k) Number	K230412
Common Name	Radiofrequency Device
Regulation Number	21 CFR 878.48400
Product Code	PBX
Regulatory Class	2
Legally Marketed Predicate Device	Indiba Diathermia RF (K161458)

Device Description:
The Symmed Elite Aesthetic device is a radiofrequency generator that is used for a number of pain related applications such as" to relieve pain, muscle spasms and increase local circulation through electrical and thermal stimulation of the treated tissues". In addition, it contains a massage function that provides temporary improvement in the appearance of cellulite. The Symmed Elite Aesthetic consists of a console plus 2 handpieces, each with 3 different size electrodes. Each handpiece is capable of being fitted with the optional massager. This allows for flexible treatment parameters throughout the working range and handpieces.

510(K) Summary
Symmed Elite Aesthetic
K230412

Indications for use:

The Symmed Elite Aesthetic is intended to provide topical heating for the purpose of elevating tissue temperature for treatment of selected medical conditions such as: relief of pain, muscle spasms, increase in local circulation. The massage device provided is intended to provide a temporary reduction in the appearance of cellulite.

Substantial Equivalence—Technological Characteristics:

Specification	Symmed	Indiba Diathermia RF	Comparison
Indications for Use	The Symmed Elite Aesthetic is intended to provide topical heating for the purpose of elevating tissue temperature for treatment of selected medical conditions such as: relief of pain, muscle spasms, increase in local circulation. The massage device provided is intended to provide a temporary reduction in the appearance of cellulite.	The Indiba Diathermia Radiofrequency Devices are intended to provide topical heating for the purpose of elevating tissue temperature for treatment of selected medical conditions such as: relief of pain, muscle spasms, increase in local circulation. The massage device provided is intended to provide a temporary reduction in the appearance of cellulite.	Same
General Description	The Symmed Elite Aesthetic Radiofrequency Device is a therapeutic device used for pain-related applications. The device consists of a console which generates a radiofrequency current which is delivered to the patient, in monopolar form, through two different types of electrodes: resistive and capacitive. The electrodes are	The Indiba Diathermia Radiofrequency Device is a therapeutic device for deep, non-invasive diathermy. The device consists of a console which generates a radiofrequency current which is delivered to the patient, in monopolar form, through two different types of electrodes: resistive and capacitive. The electrodes are inserted into a	Same

	inserted into a handle/handpiece, one handle for each kind of electrode, and the handle is connected to the console by means of a cable.	handle/handpiece, one handle for each kind of electrode, and the handle is connected to the console by means of a cable.	
Modality	Monopolar	Monopolar	Same
Output Frequency	448 kHz +/- 10%	448 kHz	Same
Input Voltage Supply	230 V a.c 50/60 Hz 115 V a.c 50/60 Hz*	(100 – 130) V~ 50/60 Hz	Same when auto-transformer is used
Maximum power	200 W	200W	Same
Operating Temperature	+10ºC to +40ºC	+10ºC to +40ºC	Same
Timer Range	60 minutes	0 – 99 minutes	Different
Electrodes	Capacitive and Resistive	Capacitive and Resistive	Same
Return	Reusable Neutral Return Electrode	Reusable Neutral Return Electrode	Same
Temperature Range for operation	+17 ºC - 30ºC	+10ºC to +40ºC	Within the range of the predicate's
Temperature range for storage and transport	No Restrictions	-20ºC to +50ºC	Different, but does not impact safety or efficacy
Display	10,2'' Color Display Touch Screen with LED Backlight	5.7 inch TFT color 320 x 240 pixels	Different, but does not impact safety or efficacy

Performance Testing

Verification and validation activities were successfully completed and establish that the Symmed Elite Aesthetic performs as intended. Testing included the following:

IEC 60601-1:2005 (Third Edition) + A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014 Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility 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

ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Software verification and validation testing was conducted to IEC 62304:2006/A1:2016, and documentation provided in accordance with FDA's Guidance or the Content of Premarket Submissions for Software Contained in Medical Devices.

Performance testing was conducted to show that frequency, impedance, voltage output, and output power all performed within the accepted range.

The Symmed Elite Aesthetic device has been validated through an in-house study to demonstrate that the device can maintain a skin surface temperature of 40°C for 10 minutes of treatment. The 3 resistive electrodes (diameters 30, 50 and 70mm), and the 3 capacitive electrodes (diameters 30, 50 and 70mm), were utilized for the evaluation of the tissue heating in both treatment modalities (capacitive and resistive respectively).

Clinical Evidence

No clinical investigations were conducted as part of this submission.

Conclusion

The indications for use, functionality, type and design of electrodes, skin temperature sensing of the Symmed Elite Aesthetic are similar to the same of the legally marketed predicate device. Performance testing conducted on the Symmed Elite Aesthetic demonstrated performance substantially equivalent to the predicate. Therefore, Symmed Elite Aesthetic device is as safe, as effective, and performs as well as or better than the legally marketed predicate device for requested interdictions for use.