June 8, 2023

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

Re: K230659
Trade/Device Name: Zionic Aesthetic
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: March 8, 2023
Received: March 9, 2023

Dear Aubrey 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: 2023.06.08 15:25:02 -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)*
K230659

Device Name
Zionic Aesthetic

Indications for Use *(Describe)*

The Zionic Aesthetic is intended to provide topical heating for the purpose of elevating tissue temperature for treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and 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.

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510(K) Summary
ZIONIC AESTHETIC
K230659

This 510(K) Summary of safety and effectiveness for the ZIONIC 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	Aubrey Thompson, Regulatory Consultant
Contact Information	aubreythompson@hoyregulatory.com (323)533-8994
Preparation Date	June 8, 2023
Device Trade Name	ZIONIC AESTHETIC
Common Name	Massager, vacuum, radio frequency induced heat
Regulation Number	878.4400
Product Code	PBX
Regulatory Class	II
Legally Marketed Predicate Device	Nuera Tight RF (K200359)

Device Description:
The ZIONIC ASTHETIC is a resistive radiofrequency device which output energy can reach up to 200W. It has two different electrodes with different sizes, to adapt the treatment to the different body areas. The electrodes roll to perform a massage while applying the radiofrequency energy.

Indications for use:
The ZIONIC AESTHETIC equipment is indicated to provide topical heating for the purpose of elevating tissue temperature for the treatment of 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.

Substantial Equivalence—Indications for Use:

Subject Device – K230659	Predicate Device -K200359	Comparison
The ZIONIC AESTHETIC is intended: • to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase local circulation; • The massage device is intended to provide a temporary reduction in the appearance of cellulite.	The NuEra Tight RF Family is intended: • to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase local circulation; • to provide, with a massage device, a temporary reduction in the appearance of cellulite.	Same

Technical Comparison	ZIONIC AESTHETIC	Nuera Tight RF – K200359	Comparison
Modes of action	Monopolar radiofrequency	Monopolar and bipolar radiofrequency	Same. The Nuera Tight RF device contains an additional bipolar handpiece that the Zionic does not.
Mechanism of action	Electromagnetic waves penetrate in exposed tissue and produce heat, increasing the temperature on a certain part of the body for therapeutic purposes.	Electromagnetic waves penetrate in exposed tissue and produce heat, increasing the temperature on a certain part of the body for therapeutic purposes.	Same
Clinical use	Prescription Use	Prescription Use	Same
Electrical Protection	Class I type BF	Class I type BF	Same
User Interface	Touchscreen	Touchscreen	Same
Firmware Controlled	Yes	Yes	Same
Type of energy	Radiofrequency waves	Radiofrequency waves	Same
Temperature Control	Yes	Yes	Same
Frequency	470kHz	470 kHz; 1 MHz; 2 MHz; 4 MHz ; 6 MHz	ZIONIC AESTHETIC working frequency is identical to one of the working frequencies of the predicate device Nuera Tight RF.
Output RF Power	Max 200 W	Max 250 W	Nearly identical. ZIONIC AESTHETIC maximum power is 20% lower than NueraTight RF, which does not generate safety or performance issues, as an output power of 200W is enough to achieve the desired temperature for the effectiveness of the treatment, and lowering the output power makes the

			device safer.
Voltage	115VAC (with external autotransformer) or 230VAC	100-240VAC	Same
Handpieces			
	ZIONIC AESTHETIC	Nuera Tight	
Transfer technology	Monopolar Resistive	Resistive and capacitive monopolar and bipolar	Predicate device includes both transfer modes, monopolar and bipolar, resistive and capacitive.
Electrode area	57/90mm	20/30/40/60/80/100mm	Very similar- the Nuera Tight device includes more variety of electrode sizes, with lower contact surface that are not included with the Zionic.

Performance Testing
Verification and validation activities were successfully completed and establish that the ZIONIC AESTHETIC control unit performs as intended. Testing included the following:

- IEC 60601-1:2005 + Corr.1:2006 + A1:2012; 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 temperature of 40 treatment C for 10 minutes of treatment for every electrode used. Performance testing was performed to demonstrate the accuracy of the output power, output frequency, and output voltage.

Clinical Evidence – N/A. No clinical studies were conducted as part of this submission.

Conclusion

The ZIONIC AESTHETIC and NueraTight RF are identical in their indications for use and nearly identical in their overall design. The key specification to compare for monopolar radiofrequecy transfer technology is the output power, which is slightly lower in the ZIONIC AESTHETIC. This difference in the maximum output power does not generate safety or performance issues, but increases the safety of the device. Both devices underwent thermal testing to show that they can maintain the desired temperature during treatment. Tests for the Zionic Aesthetic included two patients and three test sites – abdomen, thighs, and arms—and a temperature of 40° C (+2 °C) was maintained for 10 minutes of treatment. Test performed on the predicate device showed the same performance. The device maintained a temperature of 40°C (+2°C) for 15 minutes when tested on 3 different test sites and 2 patients. It can be concluded, therefore, that performance between the ZIONIC AESTHETIC and the predicate device are substantially equivalent and therefore the two devices are substantially equivalent.