



May 28, 2025

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

Re: K243716

Trade/Device Name: Zionix Pro Max (Radiofrequency)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: April 25, 2025
Received: April 25, 2025

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 (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,

James H. Digitally signed by
Jang -S James H. Jang -S
Date: 2025.05.28
18:52:23 -04'00'

James Jang, Ph.D.
Acting 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)
K243716

Device Name
Zionic ProMax (radiofrequency)

Indications for Use (Describe)

The ZIONIC PRO MAX (radiofrequency) equipment when used with the capacitive or resistive handpiece 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.

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 PRO MAX – RF
K243716

Applicant	TermoSalud
Address	Ataulfo Frieria Tarfe, 8 -33211 Gijón, Spain
Contact Person	Aubrey Thompson, Regulatory Consultant
Contact Information	aubreythompson@hoyregulatory.com
Preparation Date	May 27, 2025
Device Trade Name	ZIONIC Pro Max with Radiofrequency
Common Name	Massager, vacuum, radio frequency induced heat
Regulation Number	878.4400
Product Code	PBX,
Regulatory Class	II
Legally Marketed Predicate	Symmed Elite Aesthetic (K230412)
Legally Marketed Reference	Zionic Aesthetic (K230659)

Device Description:

The Zionic Pro Max with Radiofrequency is a non-invasive topical heating device that produces RF energy to warm subcutaneous tissue the therapeutic temperature of 40-45°C. The device includes two different type of RF handpieces, resistive and capacitive, which are connected to a console and software-powered user interface. The Zionic Pro Max adds a new capacitive handpiece and user interface to a previously cleared generation of the device.

Indications for use:

The ZIONIC PRO MAX (radiofrequency) equipment when used with the capacitive or resistive handpiece 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.

510(K) Summary
 ZIONIC PRO MAX – RF
 K243716

Indications for Use Comparison

Specification	Zionic Pro Max	Predicate Device Symmed Elite Aesthetic	Reference Device Zionic Aesthetic	Comparison
Indications for use	The ZIONIC PRO MAX (radiofrequency) equipment when used with the capacitive or resistive handpiece 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.	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 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.	. The topical heating and temporary reduction in the appearance of cellulite indications for use are identical to the predicate and reference devices.

510(K) Summary
 ZIONIC PRO MAX – RF
 K243716

Technical Specifications Comparison

Specification	Subject Device Zionic Pro Max with RF	Predicate Device Symmed Elite Aesthetic	Reference Device Zionic Aesthetic	Comparison
Mode of operation	Non-invasive monopolar radiofrequency	Non-invasive monopolar radiofrequency	Non-invasive monopolar radiofrequency	Same
RF output frequency	470KHz	448 kHz +/- 10%	N/A	Different. The Zionic Pro Max RF device's output frequency is slightly higher than the predicate device.
Capacitive RF output max power	200W	500VA	N/A	Different. But the performance testing demonstrates effectiveness.
Resistive RF output power	200W	200W	200W	Same
Electrode area	57mm/90mm	70mm/50mm/30mm	57/90mm	Different. The subject device has a larger electrode but the tissue thermal testing demonstrated equivalence to the predicate.

510(K) Summary
ZIONIC PRO MAX – RF
K243716

Performance Testing

Verification and validation activities were successfully completed and establish that the ZIONIC Pro Max 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.

Non-Clinical Testing

Tissue thermal testing was performed to demonstrate that the device can maintain a temperature of 40-45°C for 10 minutes of treatment. Bench testing was performed to demonstrate the accuracy of the output power, output frequency, and output voltage.

Conclusion

The ZIONIC Pro Max (subject device) and the Symmed Elite Aesthetic (predicate device) have identical indications for use. The Zionic Pro Max has a different capacitive maximum than the predicate which does not impact safety or efficacy of the device. The Zionic Pro Max includes electrodes that are coated (capacitive) and uncoated (resistive), while the predicate only has the resistive electrodes. . The Capacitive and Resistive electrodes have different methods of generating heat, but the mechanism of action (topical heating) is the same and performance testing demonstrates that they perform the same, maintaining a tissue temperature of 40°C for 10 minutes of treatment, the same as the predicate device.

The indications for use, functionality, type and design of electrodes, skin temperature sensing of the Zionic Pro Max are similar to or the same as the legally marketed predicate device. Performance and non-clinical testing conducted on the device demonstrates that the performance is as safe and effective, and performs as well as the legally marketed predicate device for requested indications for use and therefore is substantially equivalent to the predicate device.