July 1, 2026

Termosalud S.L.
% Connie Hoy
Regulatory Consultant
Hoy & Associates Regulatory Consulting, LLC
1830 Bonnie Way
Sacramento, California 95825

Re: K261473
Trade/Device Name: Chromix
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHS, OLP
Dated: May 4, 2026
Received: May 4, 2026

Dear Connie Hoy:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2026.07.01 14:22:07 -04'00'

Tanisha L. Hithe
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)*
K261473

Device Name
Chromix

Indications for Use *(Describe)*
The Chromix is an LED light therapy device which uses specific wavelengths of light, produced by light emitting diodes (LEDs).

It is intended to emit energy in the red and infrared region of the light spectrum to provide treatment for full face wrinkles.

The blue and red light spectrum is intended for the treatment of mild to moderate inflammatory acne.

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
K261473

Applicant:	TermoSalud S.L.
Address:	Ataulfo Friera Tarfe, 8 -33211 Gijón, Spain
Company Contact Information: Phone number: Email:	Cristina Cifuentes, Director of Quality +34-985-167-547 ccifuentes@termosalud.com
Regulatory Contact Information: Phone: Email:	Connie Hoy- Regulatory Consultant 530-908-4903 conniehoy@hoyregulatory.com
Preparation Date:	June 30, 2026
Device Trade Name:	Chromix
Product Code and Common Name:	OHS - Light Based Over-the-Counter Wrinkle Reduction OLP - Over-the-Counter Powered Light Based Laser For Acne
Regulation Number:	21 CFR 878.4810
Classification Name:	Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Regulatory Class	II
Legally Marketed Predicate Device	LightStim Elipsa – K212771

Device Description:
The Chromix applicator is an LED light therapy device consisting of 126 light sources that emit in the red, blue and IR Spectrum. The Chromix applicator is connected to a console that consists a main console that houses the micro-processor controller, touch screen user interface with the detachable Chromix applicator.

Indications for use:

The Chromix is an LED light therapy device which uses specific wavelengths of light, produced by light emitting diodes (LEDs).

It is intended to emit energy in the red and infrared region of the light spectrum to provide treatment for full face wrinkles.

The blue and red light spectrum is intended for the treatment of mild to moderate inflammatory acne.

Indication for Use Comparison

Chromix K26147	LightStimi Elipsa Predicate Device K212771	Comparison
The CHROMIX is an LED light therapy device which uses specific wavelengths of light, produced by light emitting diodes (LEDs). It is intended to emit energy in the Red and infrared region of the light spectrum to provide treatment for full face wrinkles. The blue and Red-light spectrum is intended for the treatment of mild to moderate inflammatory acne.	The LightStim Elipa is an LED light therapy device which uses specific wavelengths of light, produced by light emitting diodes (LEDs). It is intended to emit energy in the Red and infrared region of the light spectrum to provide treatment for full face wrinkles. The blue and Red-light spectrum is intended for the treatment of mild to moderate inflammatory acne	Same

Technical Comparison

	Chromix (Subject Device) K261473	LightStimi Elipsa (Predicate Device) K212771	Comparison
Classification	OHS and OLP	OHS and OLP	Same
Regulation	21 CFR 878.4810	21 CFR 878.4810	Same
Target population	People with full-face wrinkles. Women and men with mild to moderate inflammatory acne	People with full-face wrinkles. Women and men with mild to moderate inflammatory acne	Same
Anatomical sites	Entire Face	Entire Face	Identical
Where used	Professional environment	Home	Different
Emission Mode	Wavelengths within each treatment mode emitted	Unknown	Unknown

	Chromix (Subject Device) K261473	LightStimi Elipsa (Predicate Device) K212771	Comparison
	simultaneously (Wrinkle: 633nm + 850nm; Acne: 413nm + 633nm)		
Wavelengths	Wrinkle mode: RED: 633nm, 850nm Acne Mode: BLUE: 413nm, 633nm	RED:612, 645, 655 and 850nm BLUE: 410nm&645nm	Different
Output in milliwatts	Wrinkle Mode: RED: 12.4 mW/cm2 Acne Mode: BLUE: 6.2 mW/cm2	RED: 11.8mW/cm2 BLUE: 12.8mW/cm2	Different
Treatment time	Wrinkle Mode: RED: 16 minutes per area Acne Mode: BLUE: 12 minutes per area	RED: 16 minutes per area BLUE: 12 minutes per area	Same
Dose	Wrinkle Mode: RED: 11.9j/cm2 Acne Mode: BLUE: 4.46j/cm2	RED: 11.3j/cm2 BLUE: 9.2J/cm2	Same for Red Different for Blue
Total dose/treatment	Wrinkle Mode: RED: 11.9j/cm2 Acne Mode: BLUE: 4.46j/cm2	RED: 11.3j/cm2 BLUE: 9.2J/cm2	Same for Red Different for Blue
Treat Frequency	2 sessions per week	5 sessions per week	Different
Total dose/week	Wrinkle Mode: RED: 23.8 j/cm2 Acne Mode: BLUE:8.92j/cm2	RED: 56.5J/cm2 BLUE:46J/cm2	Same for Red Different for Blue

Performance Testing

Verification and validation activities were successfully completed and established that the Chromix performs as intended. Testing included the following:

- IEC 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 60601-2-57 Edition 2.0 2023-07; Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring, cosmetic and aesthetic use
- IEC 62471:2006; Photobiological safety of lamps and lamp systems
- 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

The Chromix software was determined to meet the criteria for Basic documentation level. Software verification and validation testing was conducted, and documentation provided in accordance with Industry and FDA Staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Conclusion

The subject device shares the indications for use, general design, and technical parameters as its predicate device, K212771. The small technological differences in the devices do not impact the safety or efficacy of the device. The Chromix and the LightStim Elipsa are nearly identical in their indications for use and overall design. It can be concluded, therefore, that the subject device is substantially equivalent to the predicate K212771.