September 16, 2024

Medical San Indústria de Equipamentos Médicos Ltda.
% Rodrigo Abreu
Regulatory Specialist
United Regulatory & Logistics
2950 W Cypress Creek Rd. #110
Fort Lauderdale, Florida 33309

Re: K241771
Trade/Device Name: Liftendo; Liftendo 2.0
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: GEX
Dated: June 6, 2024
Received: June 20, 2024

Dear Rodrigo Abreu:

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,

Yan Fu -S Digitally signed by Yan Fu -S
Date: 2024.09.16 10:07:13 -04'00'

for

Tanisha 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241771

Device Name
Liftendo, Liftendo 2.0

Indications for Use *(Describe)*
The Liftendo 2.0 and Liftendo are intended for the delivery of laser light to soft tissue in contact mode and non-contact mode during surgical procedures. The device's 980nm laser is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology. The device is also indicated for laser-assisted lipolysis. The device's 1470nm laser is intended for the delivery of laser light to soft tissue in non-contact mode during general surgical procedures, indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Medical San Indústria de Equipamentos Médicos Ltda.
Rua Alberto Muller, 1100 Block 20 - Rooms 404 and 406
Bairro Carneiros – Lajeado RS – Brazil - 95913-528

510(k) SUMMARY K241771

A) Submitter's Name: Medical San Indústria de Equipamentos Médicos Ltda.

Owner / Operator Registration Number: 10089008

Manufacturer Registration Number: 3029897009

Address: Rua Alberto Muller, 1100 Block 20 - Rooms 404 and 406

Bairro Carneiros – Lajeado RS – Brazil - 95913-528

B) Phone and Fax Numbers

Tel.: +55 (51) 3720-2762

Fax: +55 (51) 3720-2762

C) Contact Person:

Francis Laion de Padua
Tel.: +55 (51) 3720-2762
Email: regulatorio@medicalsan.com.br

D) Preparation Date: September 16, 2024

E) Classification:

Common / Usual Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Proprietary Name: Liftendo; Liftendo 2.0

Product Code: GEX

Class: Class II

Regulation: 21 CFR 878.4810

F) Device Description and Indications for Use

The Liftendo 2.0 and Liftendo are intended for the delivery of laser light to soft tissue in contact mode and non-contact mode during surgical procedures. The device's 980nm laser is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology. The device is also indicated for laser-assisted lipolysis. The device's 1470nm laser is intended for the delivery of laser light to soft tissue in non-contact mode during general surgical procedures, indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

G) Substantial Equivalence:

The subject device is equivalent with the following products:

510(k) Number	Model	Company
K212734	Diode laser therapy device	Triangel Rsd Limited

H) Indications for Use:

Indications for Use Comparison	
Liftendo; Liftendo 2.0	**Diode laser therapy device K212734**
The Liftendo 2.0 and Liftendo are intended for the delivery of laser light to soft tissue in contact mode and non-contact mode during surgical procedures. The device's 980nm laser is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otorlaryngology), dental procedures, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology. The device is also indicated for laser-assisted lipolysis. The device's 1470nm laser is intended for the delivery of laser light to soft tissue in non-contact mode during general surgical procedures, indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	The Diode laser therapy device is intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures. The device's 980nm laser is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology. The device is further indicated for laser assisted lipolysis. The device's 1470nm laser is intended for delivery of laser light to soft tissue in non-contact mode during general surgery procedures, indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

Although the subject device does not come with a fiber included, it is advised to utilize FDA-cleared fibers in conjunction with the device. This recommendation ensures compatibility with commonly used accessories in clinical settings, adhering to industry standards and facilitating seamless integration of the subject device into existing treatment protocols.

I) Technological Characteristics Comparison:

The predicate devices used to establish substantial equivalence for the subject device are outlined below. This section of this submission will provide a comparison of design, materials, and technical specifications of the subject device to each of the predicate devices stratified by functional modality.

GENERAL COMPARISON			
ITEM	**PROPOSED DEVICE**	**PREDICATE DEVICE 1 K212734**	**Observation**
Product Code:	GEX	GEX	Same
Regulation No.:	21 CFR 878.4810	21 CFR 878.4810	Same
Class:	2	2	Same
Classification Name:	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument	-
Trade Name:	Liftendo 2.0, Lifttendo	Diode laser therapy device	-
Manufacturer:	Medical San Industria de Equipamentos Medicos LTDA	Triangel Rsd Limited	-
Patient Population	Adult	Adult	Same

PERFORMANCE COMPARISON			
ITEM	**PROPOSED DEVICE**	**PREDICATE DEVICE 1 K212734**	**Remark**
Wavelength	980nm±5nm, 1470nm±10nm	980nm±5nm, 1470nm±10nm	Same
Output Power max.	16W/980nm±20%, 4.5W/1470nm±20%, 0.5mw/650nm	16W/980nm±20%, 4.5W/1470nm±20%, 0.5mw/650nm	Same
Aiming beam	650 nm, red 0.5 mW, user controlled intensity	650 nm, red 0.5 mW, user controlled intensity	Same
Treatment mode	Continuous or Pulse	Continuous or Pulse	Same
Power supply	110-127Vac, 60Hz	AC110V±11V, 60HZ	Gap analysis 1
Cooling	Air Cooling	Air Cooling	Same

Interval	980nm 1% ~ 100%, 1470nm 2% ~100%, continuously adjustable energy	980nm 1% ~ 100%, 1470nm 2% ~100%, continuously adjustable energy	Same
Cooling system	Air cooled	Air cooled	Same
Pulse duration	0.01s-1.00s	0.05ms-1.00s	Same
Fiber (applied part)	Not supplied with the equipment	Sterile, for single use	Gap analysis 2

SAFETY COMPARISON			
ITEM	**PROPOSED DEVICE**	**PREDICATE DEVICE 1 K212734**	**Remark**
Patient Contact Materials	Not supplied with the equipment	Treatment Probe	Gap analysis 2
Biocompatibility of materials contacting user	Not supplied with the equipment	Cytotoxicity, Comply with ISO 10993-5; Irritation, Sensitization, comply with ISO 10993-10; Aucte systemic toxicity, Pyrogen test comply with ISO 10993-11; In vitro hemolytic test comply with ISO 10993-4.	Gap analysis 2
EMC, Electrical and Laser Safety			
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same

Gap analysis 1	The proposed equipment has a wider input voltage range of 110 to 220Vac and the predicated one has only 110Vac voltage.
Gap analysis 2	The proposed equipment does not provide fiber with the device.

Substantial Equivalence Discussion:

Indication of Use:

Both the subject and predicate devices have the same intended for use, targeting the same patient population. The intended use statements for both devices align closely, demonstrating equivalence in their intended clinical applications.

Wavelength:

The subject device operates at the same wavelength range as the predicate device, ensuring comparable therapeutic effects and treatment outcomes. Both devices utilize 980nm±5nm, 1470nm±10nm for their respective procedures.

Output Power Max:

The maximum output power of the subject device matches that of the predicate device, ensuring equivalent energy delivery during treatments. Both devices provide a maximum output power of 16W/980nm±20%, 4.5W/1470nm±20%, 0.5mw/650nm to achieve optimal therapeutic results.

Aiming Beam:

Both devices are equipped with an aiming beam characteristic.

Treatment Mode:

The subject device offers treatment modes identical to those of the predicate device, enabling healthcare professionals to select the most appropriate mode for specific patient needs. Both devices support Continuous or Pulse, ensuring equivalent versatility in treatment options.

Power Supply:

Both devices are powered by the same type of power supply, ensuring consistent and reliable operation. The subject device utilizes 110VAC, which is equivalent to those of the predicate device, ensuring compatibility with standard power sources.

Cooling:

The subject device incorporates a cooling system that is comparable to the cooling system of the predicate device. Both devices employ Air Cooling, effectively managing thermal effects and ensuring patient comfort during treatments.

Interval Cooling System:

Both devices feature an interval cooling system designed to optimize treatment efficacy and patient comfort. The subject device's interval cooling system operates in a manner consistent with that of the predicate device, ensuring equivalent cooling intervals and treatment durations.

Standards Compliance:

Both the subject and predicate devices adhere to the same regulatory standards and requirements, demonstrating compliance with applicable FDA regulations and industry standards. Both devices meet or exceed IEC 60601-1, IEC 60601-2-22 and IEC 60601-1-2, ensuring equivalent levels of safety and efficacy.

Fiber Compatibility:

While the subject device does not include a fiber, it is recommended to use FDA-cleared fibers with the device, ensuring compatibility with established accessories commonly utilized in clinical practice. This recommendation aligns with industry best practices and ensures that the subject device can be seamlessly integrated into existing treatment protocols.

In conclusion, the subject device demonstrates substantial equivalence to the predicate device based on the provided information. The similarities in indications of use, technical specifications, features, and standards compliance support the assertion that the subject device is substantially equivalent to the predicate device and thus merits FDA 510(k) clearance.

K) Non-clinical Testing:

Conducting non-clinical tests on the subject device, as per international standard IEC 60601-2-22, ensures its reliability, safety, and performance in real-world scenarios. These tests evaluate functionality, environmental compatibility, safety features, and user interface, confirming the device's suitability for diverse non-clinical settings. Adhering to this standard demonstrates the device's accuracy and regulatory compliance outside clinical environments, bolstering user confidence and minimizing risks. As part of the substantial equivalence, the predicate also demonstrates non-clinical tests based on the IEC 60601-2-22.

Additionally, conducting tests in accordance with IEC 60601-1 and IEC 60601-1-2 standards further ensures the device's compliance with essential safety and electromagnetic compatibility requirements. IEC 60601-1 focuses on the basic safety and essential performance of medical electrical equipment, while IEC 60601-1-2 addresses the electromagnetic disturbances and immunity of the device. These comprehensive evaluations enhance the overall safety profile and operational integrity of the device, providing additional assurance to users and stakeholders.

L) Conclusions

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submissions, the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K212734