January 5, 2024

LMG Lasers Comercio, Importacao e Exportacao Ltda
% Rodrigo Abreu
Regulatory Specialist
United Regulatory Inc
12343 NW 25th St
Coral Springs, Florida 33065

Re: K221766
Trade/Device Name: Solon
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: December 6, 2023
Received: December 6, 2023

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.

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,

Jianting Wang -S

Digitally signed by Jianting Wang -S
Date: 2024.01.05 11:17:37 -05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221766

Device Name
Solon

Indications for Use *(Describe)*
Solon is intended to be use in dermatology, cosmetic surgery, and other surgical applications according to the different handpieces.
The specific indications should reference to the indications of each handpiece.
1) Pro handpiece:
• Incision, excision, ablation, vaporization of soft tissue
• The non-ablative treatment of facial wrinkles
2) Multistation Handpiece:
• Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB.
3) Vektra QS Handpiece:
• Tattoo Removal: Dark Ink: (Black & Blue)
• Nevus of Ota
• Skin resurfacing procedures for the treatment of acne scars and wrinkles
4) IPL Handpiece:
The Intense Pulsed Light wavelengths are 515-1200 nm
• Multiwave: 650-1200 nm
The removal of unwanted hair from skin types l-V, and to effect stable long-term, or permanent hair reduction in skin types I - V through selective targeting of melanin in hair follicules.
• Expert Light: 570- 1200nm
The treatment of benign pigment (epidermal and cutaneous) lesions, such as warts.
• Expert Light: 515-1200nm
The treatment of benign vascular lesions including port wine stains, hemangiomas, facial, truncal anf leg telangiectasias, rosacea, melasma, angiomas and spider aglormas, polkilorderma of civatte, leg veins and venous malformations.

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.

LMG Lasers Comércio, Importação e Exportação Ltda
Rua Sebastião Monteiro Ferraz Nº 421 – Polo Industrial
Guaxupé, MG Brazil CEP: 37800-000
Tel.: +55 (35) 3559 2500

510(k) SUMMARY
K221766

A) Submitter's Name: LMG Lasers Comércio, Importação e Exportação Ltda

Owner / Operator Registration Number: 10059503

Manufacturer Registration Number: Not available yet.

Address: Rua Sebastião Monteiro Ferraz Nº 421 – Polo Industrial

Guaxupé / MG CEP: 37800-000

B) Phone and Fax Numbers

Phone: +55 (35) 3559 2499

Fax: (305) 393-8429

C) Contact Person:

Leticia de Paula Souza Moraes

Tel.: +55 (35) 3559 2500

D) Preparation Date: January 3rd, 2024

E) Classification Name:

Common / Usual Name: Powered laser surgical instrument

Proprietary Name: Solon

Product Code: GEX

Class: Class II

Regulation: 21 CFR 878.4810

F) Device Description

The Solon system is a modular multifunction device. The equipment can be used in dermatology, and aesthetic surgery according to the different handpieces. The Solon system has five laser handpieces of Er:YAG laser, Long Pulse Nd:YAG Laser, and Q-Switch Nd:YAG Laser, and two IPL handpiece.

G) Substantial Equivalence:

The Solon is equivalent with the following products:

510(k) Number	Model	Company
K113018	APOLLO V+ Medical Platform	Beijing Syntech Laser Co., Ltd.

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H) Indications for Use:

Indications for Use Comparison
Solon
Solon is intended to be use in dermatology, cosmetic surgery, and other surgical applications according to the different handpieces. The specific indications should reference to the indications of each handpiece. **1) Pro handpiece:** • Incision, excision, ablation, vaporization of soft tissue • The non-ablative treatment of facial wrinkles **2) Multistation Handpiece:** • Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. **3) Vektra QS Handpiece:** • Tattoo Removal: Dark Ink: (Black & Blue) • Nevus of Ota • Skin resurfacing procedures for the treatment of acne scars and wrinkles **4) IPL Handpiece:** The Intense Pulsed Light wavelengths are 515-1200 nm • **Multiwave: 650-1200 nm** The removal of unwanted hair from skin types I-V, and to effect stable long-term, or permanent hair reduction in skin types I - V through selective targeting of melanin in hair follicules. • **Expert Light: 570- 1200nm** The treatment of benign pigment (epidermal and cutaneous) lesions, such as warts. • **Expert Light: 515-1200nm** The treatment of benign vascular lesions including port wine stains, hemangiomas, facial, truncal anf leg telangiectasias, rosacea, melasma, angiomas and spider aglormas, polkilorderma of civatte, leg veins and venous malformations.

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I) Technological Characteristics Comparison:

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

Device Brand and Common Name	**Solon**	**APOLLO V+ Medical Platform**	**Substantial Equivalence Discussion**
510k #	Not assigned yet	K113018	NA
Classification	II	II	Identical
Regulation #	21 CFR 878.4810	21 CFR 878.4810	Identical
Product Code	GEX	GEX	Identical
Classification Name	Powered laser surgical instrument	Powered laser surgical instrument	Identical
Patient Population	Adult	Adult	Identical
Prescription Use	YES	YES	Identical
Environment	Clinic/doctor's office	Clinic/doctor's office	Identical
Applicable Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-22	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-22	Identical
Materials	PVC, rubber, electronic components	PVC, rubber, electronic components	Identical

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Biocompatibility	Cytotoxicity Sensitization Irritability	Cytotoxicity Sensitization Irritability	Identical
Device Sterilization	Not required	Not required	Identical
Device physical design			Similar design
Power Supply	AC Voltage input: 120 V, 50/60 Hz	AC Voltage input: 120 V, 50/60 Hz	Identical
Max Output Power	1000VA	1000VA	Identical
Probe types	IPL, Lasers	IPL, Lasers	Identical
Control	Touch screen, footswitch	Touch screen, footswitch	Identical
Working mode	Interval and pulse	Interval and pulse	Identical
Operative Panel	Color LCD	Color LCD	Identical

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Contact Cooling	Water cooling and air cooling: 0-5°C	Water cooling and air cooling: 0-5°C	Identical
Dimensions	442mm x 385mm x 1080mm	420mm x 410mm x 1140mm	Similar Design
Laser classification	Class 4	Class 4	Identical
Laser mode	Multimode	Multimode	Identical
Weight	54,5Kg	48 kg	Similar Design
Handpiece Specification	see the explanation of each handpiece	see the explanation of each handpiece	Identical

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SE Discussion:

In accordance with the requirements outlined in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Food and Drug Administration (FDA) regulations, this discussion aims to establish the substantial equivalence of Solon, a medical device, to its predicate(s). The predicate(s) serve as a reference point for evaluating whether Solon raises any safety or effectiveness concerns and whether it meets the necessary criteria for substantial equivalence. In this discussion, we will provide a comprehensive comparison between Solon and its predicate(s) with a focus on technology characteristics, handpieces, safety standards compliance, and performance parameters.

Technology Characteristics:
Solon and its predicate(s) share striking similarities in technology characteristics. Both devices are designed for similar applications and serve identical functions within the medical field. The key technology parameters, such as energy specification, spot sizes, maximum energy density, beam divergence, and other energy-related parameters, are closely aligned between Solon and its predicate(s). This similarity in technology characteristics underscores the potential for substantial equivalence.

Handpieces:
The handpieces used with Solon and its predicate(s) are remarkably similar in design, form, and function. They are tailored to accommodate the respective devices' energy parameters and application requirements. The physical attributes, ergonomic features, and compatibility with the devices are nearly identical. Therefore, it can be established that the handpieces are substantially equivalent, contributing to the overall equivalence of Solon to its predicate(s).

Safety Standards Compliance:
Both Solon and its predicate(s) adhere rigorously to established safety standards and regulations mandated by the FDA and other relevant authorities. These standards include but are not limited to those governing electrical safety, electromagnetic compatibility, and user safety. The manufacturers have demonstrated their commitment to ensuring the safety of patients and operators alike. As a result, Solon is in substantial compliance with safety standards, mirroring the predicate(s) in this regard.

Performance Parameters:
The performance parameters of Solon closely mirror those of its predicate(s). Comprehensive testing and evaluation have demonstrated that Solon operates within the specified performance criteria and meets or exceeds the standards set by the predicate(s). The device consistently delivers the desired energy output, spot sizes, energy density, and beam divergence parameters as intended. This consistency in performance parameters reinforces the argument for substantial equivalence.

Conclusion:
In summary, the comparison presented above highlights that Solon achieves substantial equivalence to the predicate(s) without raising any safety or effectiveness concerns. The technology characteristics, handpieces, safety standards compliance, and performance parameters align closely between Solon and its predicate(s). This alignment underscores Solon's eligibility for substantial equivalence, paving the way for its evaluation and potential approval by the FDA for its intended medical The substantial equivalence of Solon to the predicate(s) ensures that it can provide patients with access to safe and effective medical treatments, benefiting healthcare providers and the broader medical community.

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J) Performance and Safety Evaluation:

In order to reach high performance, safety and effectiveness the device Solon was developed, as well produced in compliance with recognized international regulations and standards for the medical device industry.

Description	**Standard Number**
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	IEC 60601-1:2005 +CORR.1:2006 +CORR.2:2007+A1:2012
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	IEC 60601-1-2 Edition 4.1 2020-09
Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	IEC 60601-2-22 Edition 3.1 2012-10
Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	ISO 10993-1: 2018
Biological Evaluation of Medical Devices - Tests for In vitro Cytotoxicity.	ISO 10993-5: 2009/(R)2014
Biological Evaluation of Medical Device – Tests for Irritation and Skin Sensitization.	ISO 10993-10: 2010/(R)2014

K) Non-clinical Testing:

No clinical trial was performed.

L) Conclusion:

Based on compliance with the international standard and regulation mentioned above, the device Solon demonstrate safety, effectiveness and equivalent to the predicates above.