March 21, 2025

Solar Ls Cjsc
Dmitry Kiselevich
Official Correspondent
4 Stebeneva lane
Minsk, 220024
Belarus

Re: K243630
Trade/Device Name: Medical Laser System Incanto / Evoline Platinum /Evoline
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: November 25, 2024
Received: November 25, 2024

Dear Dmitry Kiselevich:

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: 2025.03.21 10:37:24 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243630

Device Name
Medical Laser System Incanto / Evoline Platinum /Evoline

Indications for Use *(Describe)*

Indications for use:

Alexandrite laser (755nm):

- Temporary hair reduction.
- Stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles.
- Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,9 and 12 months after the completion of a treatment regime on all skin types (Fitzpatrick I-VI) included tanned skin.
- Treatment of benign pigmented lesions.
- Treatment of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).

Nd:YAG laser (1064nm):

- Removal of unwanted hair for stable long term or permanent hair reduction and for treatment of PFB. The laser are indicated on all Skin Types Fitzapatrick I-VI including tanned skin.
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to, port wine stains, hemangioma, warts, teleangiectasia, rosacea, venus lake, leg veins and spider veins.
- Coagulation and hemostasis of soft tissue.
- Benign pigmented lesions such as, but not limited to, lentigos, (age spots), solar lentigos (such spots), cafe au lait macules, seborrheic keratosis, nevi, cloasma, verrucae, skin tags, keratosis and plaques.
- Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- Treatment of wrinkles.
- Temporary increase of clear nail in patients with onychomycosis (e.g.; dermatophytes, Trichophyton rubrumn and T. mentagrophytes, and/or yeast Candida Albicans, etc.)

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
K243630
Medical Laser System Incanto / Evoline Platinum / Evoline

I. SUBMITTER

SOLAR LS CJSC
4 Stebeneva lane
Minsk City 220024,
Republic of Belarus

Contact Person: Dmitry Kiselevich

Tel: +375173788183
E-mail: d_kiselevich@solarls.eu

Date of preparation: March 17th, 2025

II. DEVICE

Trade Name:	Medical Laser System Incanto / Evoline Platinum / Evoline
Common or Usual Name:	Surgical Laser Device
Product code:	GEX
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology 21 C.F.R. § 878.4810, Device Class II

III. PREDICATE DEVICE

Manufacturer	El. En. S.p.A.
Trade Name:	DEKA AGAIN PRO family
Common or Usual Name:	Surgical Laser Device
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology 21 C.F.R. § 878.4810, Device Class II
Premarket Notification:	K233090 Oct 27th, 2023

Manufacturer	CUTERA, INC.
Trade Name:	GenesisPlus
Common or Usual Name:	Surgical Laser Device
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology 21 C.F.R. § 878.4810, Device Class II
Premarket Notification:	K122493 May 15th, 2013

IV. DEVICE DESCRIPTION

The laser systems (modifications INCANTO, EVOLINE, EVOLINE PLATINUM), provides 1064nm Nd:YAG radiation and 755nm Alexandrite radiation. Availability of two wavelengths (1064nm and 755nm) in one laser system allows to select the most optimal laser radiation exposure type for different skin types.

V. INDICATIONS FOR USE

Indications for use:

Alexandrite laser (755nm):

- Temporary hair reduction.
- Stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles.
- Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,9 and 12 months after the completion of a treatment regime on all skin types (Fitzpatrick I-VI) included tanned skin.
- Treatment of benign pigmented lesions.
- Treatment of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).

Nd:YAG laser (1064nm):

- Removal of unwanted hair for stable long term or permanent hair reduction and for treatment of PFB. The laser are indicated on all Skin Types Fitzapatrick I-VI including tanned skin.
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to, port wine stains, hemangioma, warts, teleangiectasia, rosacea, venus lake, leg veins and spider veins.
- Coagulation and hemostasis of soft tissue.
- Benign pigmented lesions such as, but not limited to, lentigos, (age spots), solar lentigos (such spots), cafe au lait macules, seborrheic keratosis, nevi, cloasma, verrucae, skin tags, keratosis and plaques.
- Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- Treatment of wrinkles.
- Temporary increase of clear nail in patients with onychomycosis (e.g.; dermatophytes, Trichophyton rubrumn and T. mentagrophytes, and/or yeast Candida Albicans, etc.).

VI. COMPARISON OF TECHNOLOGICAL CHARATERISTICS WITH THE PREDICATE DEVICE

Feature	**Proposed device**	**Predicate device (K233090)**	**Predicate device (K122493)**
Device Name	Medical Laser System Incanto / Evoline Platinum / Evoline	DEKA AGAIN PRO family	Cutera GenesisPlus Laser System
Product Code	GEX	GEX	GEX
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Device Class	Class II	Class II	Class II
Indication for Use	Indications for use: Alexandrite laser (755nm): - Temporary hair reduction. - Stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles. - Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,9 and 12 months after the completion of a treatment regime on all skin types (Fitzpatrick I-VI) included tanned skin. - Treatment of benign pigmented lesions. - Treatment of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).	The DEKA AGAIN PRO family is a medical laser family intended for: Alexandrite laser (755nm): - Temporary hair reduction. - Stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles. - Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,9 and 12 months after the completion of a treatment regime on all skin types (Fitzpatrick 1-VI) included tanned skin. - Treatment of benign pigmented lesions. - Treatment of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).	The Cutera GenesisPlus Nd:YAG laser is intended for use in the medical specialties of general and plastic surgery, dermatology, endloscopiclaproscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonarythoracic surgery, podiatry and urology for surgical and aesthetic applications. Dermatology: The Cutera GenesisPlus laser is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, rosacea/ diffuse redness, poikiloderma of civatte, scar reduction (including hypertropic and keloid scars), and warts. The Cutera GenesisPlus laser is also indicated for the

Feature	**Proposed device**	**Predicate device (K233090)**	**Predicate device (K122493)**
	Nd:YAG laser (1064nm): - Removal of unwanted hair for stable long term or permanent hair reduction and for treatment of PFB. The laser are indicated on all Skin Types Fitzapatrick I-VI including tanned skin. - Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to, port wine stains, hemangioma, warts, teleangiectasia, rosacea, venus lake, leg veins and spider veins. - Coagulation and hemostasis of soft tissue. - Benign pigmented lesions such as, but not limited to, lentigos, (age spots), solar lentigos (such spots), cafe au lait macules, seborrheic keratosis, nevi, cloasma, verrucae, skin tags, keratosis and plaques. - Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. - Reduction of red pigmentation in hypertrophic and keloid scars where	Nd:YAG laser (1064nm): - Removal of unwanted hair for stable long term or permanent hair reduction and for treatment of PFB. The laser are indicated on all Skin Types Fitzapatrick 1-VI including tanned skin. - Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to, port wine stains, hemangioma, warts, teleangiectasia, rosacea, venus lake, leg veins and spider veins. - Coagulation and hemostasis od soft tissue. - Benign pigmented lesions such as, but not limited to, lentigos, (age spots), solar lentigos (such spots), cafe au lait macules, seborrheic keratosis, nevi, cloasma, verrucae, skin tags, keratosis and plaques. - Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. - Reduction of red pigmentation in hypertrophic and keloid scars where	treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles. The GenesisPlus laser is indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin. Podiatry: Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including: * Matrixectomy * Periungual and subungual warts * Plantar warts * Radical nail excision * Neuromas The Cutera GenesisPlus laser is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g.; dermatophytes, Trichophyton rubrumn and T. mentagrophytes, and/or yeast Candida Albicans, etc.).

Feature	**Proposed device**	**Predicate device (K233090)**	**Predicate device (K122493)**
	vascularity is an integral part of the scar. - Treatment of wrinkles. - Temporary increase of clear nail in patients with onychomycosis (e.g.; dermatophytes, Trichophyton rubrumn and T. mentagrophytes, and/or yeast Candida Albicans, etc.).	vascularity is an integral part of the scar. - Treatment of wrinkles.	
Laser Type	Alexandrite laser Nd:YAG laser	Alexandrite laser Nd:YAG laser	Nd:YAG laser
Laser Classification	Class IV	Class IV	Class IV
Laser Wavelength	Alexandrite laser: 755 nm Nd:YAG laser: 1064 nm	Alexandrite laser: 755 nm Nd:YAG laser: 1064 nm	Nd:YAG laser: 1064 nm
Laser Delivery System	Handpiece	Handpiece	Handpiece
Laser firing Controls	LCD color Touchscreen Footswitch	LCD color Touchscreen Footswitch	LCD color Touchscreen Footswitch
*Fluence (Max)**	600 J/cm^2	600 J/cm^2	15-18 J/cm^2
Frequency	0.5 to 10 Hz	Up to 12 Hz	2-3 Hz
Pulse width (Max)	0.3 to 200 ms	0.2 to 300 ms	0.3 ms

Feature	**Proposed device**	**Predicate device (K233090)**	**Predicate device (K122493)**
Spot Size (diameter millimeter)	2 mm, 3 mm, 4 mm, 6 mm, 8 mm, 10 mm, 12 mm, 14 mm, 16 mm, 18 mm, 20 mm, 22 mm, 24 mm	2.5 mm 5 mm 7 mm 10 mm 12 mm 14 mm 15 mm 16 mm 18 mm 20 mm 22 mm 24 mm 30 mm	5 mm
Cooling	water and air	water and air	water and air

* Maximum fluence is not available for all spot sizes.

VII. PERFORMANCE DATA

The Medical Laser System Incanto / Evoline Platinum / Evoline has been determined through engineering testing to verify laser energy output and electrical safety.

Electrical safety and electromagnetic compatibility

The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014+AMD1:2020 Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60825-1:2014 Safety of Laser products-Part 1: Equipment classification and requirements

IEC 60601-2-22:2019 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Content of Premarket Submissions for Device Software Functions, "Guidance for Industry and Food and Drug Administration Staff." The software for this device was considered as a "Basic Documentation" level of concern since a failure of the software could result in minor injury to a patient or to a user of the device.

Sterilization and Shelf-Life

The proposed device is not provided sterile and does not need to be sterilized. The handpiece and the body are cleaned with a soft cloth moistened with ethanol of 70% strength or higher. The proposed device is reusable and does not have a restricted shelf-life.

Biocompatibility

The handpiece tip may be contact with the intact skin of patients. According to FDA guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process "" three biological effects were determined in following three test: Cytotoxicity, Sensitization and Irritation.

Three biological effects, cytotoxicity, sensitization and irritation testing, were performed and test results did not identify any biological response or risk. The Medical Laser System Incanto / Evoline Platinum / Evoline meets the ISO 10993-1 standard requirements for biocompatibility and no further characterization testing is required.

VIII. CONCLUSION

The Medical Laser System Incanto / Evoline Platinum / Evoline shares similar indication of use, the same design feature, the similar technological characteristics, and the same principles of operation as its predicate devices. The minor differences between the proposed device and the predicate devices have been conducted related non-clinical tests as part of the design validation to identify that they are not sufficient to raise new questions of safety. Based on above analysis, the Medical Laser System Incanto / Evoline Platinum / Evoline is as safe, as effective, and performs as well as the cited predicate devices K233090 and K122493.