March 8, 2024

Cynosure, LLC.
Cynthia Aguirre
Regulatory Affairs Specialist II
5 Carlisle Rd.
Wesford, Massachusetts 01886

Re: K240396
Trade/Device Name: Elite iQ PRO (M122K1)
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: February 7, 2024
Received: February 8, 2024

Dear Cynthia Aguirre:

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,

Tanisha L. Hithe -S
Tanisha L. Hithe -S
2024.03.08
12:34:41 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical & 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)*
K240396

Device Name
Elite iQ PRO

Indications for Use *(Describe)*

755nm:
The Elite iQ PRO Laser System is indicated for stable long-term or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing when measured at 6, 9 or 12 months after the completion of a treatment regime. It is used for skin types (Fitzpatrick I-VI) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles.

1064nm:
The Elite iQ PRO Laser System is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venous lakes, leg veins, spider veins and poikiloderma of Civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigines (age spots), solar lentigines (sunspots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratosis and plaques.

The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

Additionally, the laser is indicated for the treatment of pseudo folliculitis barbae (PFB) and for stable long-term or permanent hair reduction. Permanent hair reduction is defined as 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.
The Skintel Reader is intended as an objective measurement tool for examining skin melanin content for determining and setting a test spot starting fluence.

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.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for Cynosure Elite iQ PRO (K240396)

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) Submitter Information	
Applicant	Cynosure, LLC
Address	5 Carlisle Road, Westford MA, 01886
Phone Number	781-993-2454
Fax Number	978-256-6556
Establishment Registration Number	1222993
Contact Person	Cynthia Aguirre
Preparation Date	March 7, 2024
807.92(a)(2) Name of Device	
Trade or Proprietary Name	Elite iQ™ PRO
Common or Usual Name	Medical Laser System
Classification Name	Powered Laser Surgical Instrument
Classification Panel	General & Plastic Surgery
Regulation	21 CFR 878.4810
Regulatory Class	II
Product Code(s)	GEX
807.92 (a)(3) Legally marketed device(s) to which equivalence is claimed	
Predicate Devices	Elite iQ™ Laser System (K193426) DEKA AGAIN PRO (K233090)
807.92(a)(4) Device Description	
	The Elite iQ™ PRO workstation is a dual wavelength system that delivers laser energy in both the Nd:YAG (1064-nm) and Alexandrite (755-nm) wavelengths. Through various spot sizes, fluences and repetition rates, the system offers hair removal treatment and aesthetic treatments across all skin types. An Alexandrite standalone workstation is also available for purchase. The Elite iQ PRO delivers the laser energy through a lens-coupled optical fiber with a wide range of interchangeable, quick-release laser handpieces with

	electronic spot recognition. The Elite iQ PRO also includes the Skintel® Melanin Reader for objective measurement of the melanin content of skin. The locking casters allow this stand-alone laser system to be secured in place, as well as to be conveniently moved or transported. When not in use, handpiece components and other system components can be stowed in the storage area located in the side drawer. All system connections, such as the foot switch and remote interlock connections, are located on the rear of the laser. This includes all applicable device labels. User-selectable controls and functions are located on the front of the laser. Elite iQ PRO software features include a Windows® operating system, LCD touch screen and a state-of-the-art graphic user interface. The software of the device was changed to update the fluence levels for the handpieces in order to support the new 30mm handpiece. The new 30 mm handpiece is also part of the DEKA AGAIN PRO device (K233090). The new fluence levels are within range of the previously approved ranges in the Elite iQ device (K193426). The software was also updated to reflect the Elite iQ PRO branding. There are no changes to the principle of use of the device compared to the predicates Elite iQ Laser System (K193426) and DEKA AGAIN PRO (K233090). The labeling of the device has been updated to reflect the name of the device Elite IQ PRO Laser System.
807.92(a)(5) Intended Use of the Device	
	755nm: The Elite iQ PRO Laser System is indicated for stable long-term or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing when measured at 6, 9 or 12 months after the completion of a treatment regime. It is used for skin types (Fitzpatrick I-VI) including tanned

	skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles. 1064nm: The Elite iQ PRO Laser System is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venous lakes, leg veins, spider veins and poikiloderma of Civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigines (age spots), solar lentigines (sunspots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratosis and plaques. The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles. Additionally, the laser is indicated for the treatment of pseudo folliculitis barbae (PFB) and for stable long-term or permanent hair reduction. Permanent hair reduction is defined as 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. The Skintel Reader is intended as an objective measurement tool for examining skin melanin content for determining and setting a test spot starting fluence. There have been no changes to the intended use of the device compared to the predicate Elite iQ Laser System (K193426).

The following verification and validation activities have been performed on the modified device.

- Test according to AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, Cl:2009/(R)2012 and A2:2010/(R)2012 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.

- Test according to IEC 60601-1-2 Ed. 4.1 :2020-09 – Medical electrical equipment – part 1-2: General Requirements for Basic Safety and Essential Performance– Collateral standard: Electromagnetic Disturbances – Requirements and tests.

- Test according to IEC 60601-2-22 Edition 3.1 2012-10 - Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

- Test according to IEC 60825-1:2014 Safety of laser products – Part 1: Equipment classification and requirements

Characteristic	Cynosure Elite iQ PRO (K240396)	DEKA AGAIN PRO Family (K233090)	Cynosure Elite iQ (K193426)
Indications for Use	**755nm:** The Elite iQ laser is indicated for stable long-term or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing when measured at 6, 9 or 12 months after the completion of a treatment regime. It is used for skin types (Fitzpatrick I-VI) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles. **1064nm:** The Elite iQ laser is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venous lakes, leg veins, spider veins and poikiloderma of Civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigines (age spots), solar lentigines (sunspots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratosis and plaques.	**Alexandrite 755 nm laser:** 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. Treatment of benign pigmented lesions. Treatment of wrinkles. Photocoagulation of dermatological vascular lesions (suchs port-wine stains, hemangiomas, telangiectasias). **Nd:YAG 1064 nm laser:** Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The lasers are indicated on all Skin Types Fitzpatrick 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 (sun spots), café au lait macules, seborrheic keratosis, nevi, cloasma, verrucae, skin tags, keratosis and plaques. The laser is indicated for	**755nm:** The Elite iQ laser is indicated for stable long-term or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing when measured at 6, 9 or 12 months after the completion of a treatment regime. It is used for skin types (Fitzpatrick I-VI) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles. **1064nm:** The Elite iQ laser is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venous lakes, leg veins, spider veins and poikiloderma of Civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigines (age spots), solar lentigines (sunspots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratosis and plaques.

Characteristic	Cynosure Elite iQ PRO (K240396)	DEKA AGAIN PRO Family (K233090)	Cynosure Elite iQ (K193426)
	The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles. Additionally, the laser is indicated for the treatment of pseudo folliculitis barbae (PFB) and for stable long-term or permanent hair reduction. Permanent hair reduction is defined as 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. The Skintel Reader is intended as an objective measurement tool for examining skin melanin content for determining and setting a test spot starting fluence.	pigmented lesions to reduce lesion size, or patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. The laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Treatment of wrinkles.	The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles. Additionally, the laser is indicated for the treatment of pseudo folliculitis barbae (PFB) and for stable long-term or permanent hair reduction. Permanent hair reduction is defined as 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. The Skintel Reader is intended as an objective measurement tool for examining skin melanin content for determining and setting a test spot starting fluence
Laser Type	Alexandrite and Nd:YAG laser	Alexandrite and Nd:YAG laser	Alexandrite and Nd:YAG laser
Wavelength	1064nm (Nd:YAG) and 755nm (Alexandrite)	1064nm (Nd:YAG) and 755nm (Alexandrite)	1064nm (Nd:YAG) and 755nm (Alexandrite)
Treatment Activation	Footswitch or Fingerswitch	Footswitch or Fingerswitch	Footswitch or Fingerswitch
Rx/OTC	Prescription	Prescription	Prescription
Maximum Fluence	600 J/cm²	600 J/cm²	600 J/cm²
Repetition Rate	0.5 Hz – 12Hz	0.5 Hz – 12Hz	0.5 Hz – 10Hz

Characteristic	Cynosure Elite iQ PRO (K240396)	DEKA AGAIN PRO Family (K233090)	Cynosure Elite iQ (K193426)
Pulse Duration	0.5ms – 300ms	0.2ms – 300ms	0.5ms – 300ms
Handpiece (Spot) Size	2.5mm, 5mm, 7mm, 10mm, 12mm, 15mm, 18mm, 20mm, 22mm, 24mm, & 30mm	2.5mm, 5mm, 7mm, 10mm, 12mm, 15mm, 16mm, 18mm, 20mm, 22mm, 24mm, & 30mm	2.5mm, 5mm, 7mm, 10mm, 12mm, 15mm, 18mm, 20mm, 22mm, & 24mm
Patient Contacting Material	**Handpiece Tips:** 316 Stainless Steel	**Handpiece Tips:** 316 Stainless Steel	**Handpiece Tips:** 316 Stainless Steel
Input Voltage	208-240 V~, 5500 VA, 50-60 Hz, Single Phase	208-240V~, 6900 VA (max) 50-60Hz, single phase	208-240 V~, 5500 VA, 50-60 Hz, Single Phase
Max Power Output	4.0 mW	4.0 mW	4.0 mW
Cold Air Chiller Device Compatible	Yes	Yes	Yes

Skintel Melanin Reader Specifications

Description	Elite iQ PRO	Elite IQ
	(K240396)	**(K193426)**
Patent Contacting Material	Cycoloy 6200, Sapphire glass	Cycoloy 6200, Sapphire glass
Light Source	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)
Wavelengths	630 nm, 700 nm, 880 nm	630 nm, 700 nm, 880 nm

Measurement Area	7 x 11 mm^2	7 x 11 mm^2
Melanin Index Range	0-99	0-99
Accuracy	+/- 5 Melanin Index (MI)	+/- 5 Melanin Index (MI)
Measurement Time	Less than one (1) second per measurement	Less than one (1) second per measurement
AC Charger Power Requirements	100 V – 240 V, 50-60 Hz @ 1 A	100 V – 240 V, 50-60 Hz @ 1 A
Battery-Operated Mode	Electrical Rating: 3.7 VDC internal battery	Electrical Rating: 3.7 VDC internal battery
Dimensions	1.2 in x 2 in x 8.5 in (3 cm x 5 cm x 21.5 cm)	1.2 in x 2 in x 8.5 in (3 cm x 5 cm x 21.5 cm)
Weight	125 g (4.4 oz)	125 g (4.4 oz)

Conclusion

The Elite iQ PRO Laser System shares similar technological characteristics, theory of operation, design, and indications with its predicates Elite iQ (K193426) and DEKA AGAIN PRO (K233090) as described in the tables above. Like its predicates, the Elite iQ PRO utilizes 1064nm (Nd:YAG) and 755nm (Alexandrite) lasers for the removal of hair, vascular lesions, pigmented lesions, etc. Additionally, the Elite iQ PRO is now able to reach a repetition rate of 12 Hz and has a new 30 mm handpiece similar to the DEKA AGAIN PRO. There are no changes to the Skintel Melanin Reader.

Based on the information presented above, it is determined that the proposed Elite iQ PRO Laser System is substantially equivalent to its predicate devices.