March 9, 2020

Cynosure LLC
Michael King
Regulatory Affairs Specialist II
5 Carlisle Road
Westford, Massachusetts 01886

Re: K193426
Trade/Device Name: Elite iQ
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 9, 2019
Received: December 10, 2019

Dear Michael King:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Neil R.P. Ogden, MS
Assistant Director, THT4A4
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: 06/30/2020
See PRA Statement below.

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

Device Name
Elite iQ

Indications for Use *(Describe)*

755nm:
The Elite iQ 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 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.

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510(k) Summary for Cynosure Elite iQ

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	Michael King
Preparation Date	December 09, 2019
807.92(a)(2) Name of Device	
Trade or Proprietary Name	Elite iQ™
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	Cynosure Elite+ (K141425) Deka Synchro Repla:Y (K150516) Cynosure Vectus (K120622)
807.92(a)(4) Device Description	
	The Elite iQ™ 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 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 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 software features include a Windows® operating system, LCD touch screen and a state-of-the-art graphic user interface.
807.92(a)(5) Intended Use of the Device	
	755nm: The Elite iQ 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 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.

807.92(b)(1) Non-clinical tests submitted

The following non-clinical tests have been included in this 510k submission in determination of substantial equivalence between the test device and the referenced predicates.

Biocompatibility Testing
Biocompatibility testing was conducted in accordance with ISO 10993-1 to demonstrate the Elite iQ handpieces are comprised of safe, biocompatible materials.

Performance Testing – Bench
The Elite iQ Laser System incorporates a Hair Removal Treatment Guidance Mode where the user enters the spot size, Fitzpatrick Skin type, and hair type (coarse, medium, or fine hair) and the system recommends starting settings, namely fluence and pulse width, to begin a test spot. These recommended settings have been created based on previous user experience with the Elite+ Laser System and are conservative and intended to give a less experienced user a starting point for a test spot. Users can always modify these settings based on their knowledge and experience to best suit a patient's individual skin type.

A validation study was performed to ensure the recommended test spot settings in the Hair Removal Treatment Guidance Mode are a safe starting point. E. Victor Ross MD, affiliated with Scripps Green Hospital in San Diego, CA, performed this validation study using the Elite+ Laser System. The Elite+ Laser System can achieve the same fluence and pulse width settings recommended in the Elite iQ Hair Removal Treatment Guidance Mode, thus the results of this study are applicable to the Elite iQ Laser System. Each skin type, hair type, and spot size combination were tested in this study. The subjects chosen were at the high end of the recommended skin type range in order to account for the situation with the highest risk profile for a given characteristic. Patients were then evaluated 48-72 hours post treatment for any undesirable effects resulting from the treatment, such as blistering scarring, hypopigmentation, or hyperpigmentation. Refer to Section 018 – Performance Testing Bench for the test report. Results showed no undesirable or unexpected AEs from test spots.

Electromagnetic Compatibility and Electrical Safety
Electrical safety testing for the Elite iQ was also completed to prove the safe use of the device. The following test reports are available in Section 17 – Electromagnetic Compatibility and Electrical Safety.

- IEC 60601-1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performances
- IEC 60601-1-2, Medical Electrical Equipment – Part 1 -2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – requirements and tests

- IEC 60601-1-6, Edition 3.1 & EN 62366-1, Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
- IEC 60601-2-22, Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825-1, Safety of Laser Products - Part 1: Equipment classification and requirements

807.92(b)(2) Clinical tests submitted – N/A – No clinical tests submitted

807.92(b)(3) Conclusions drawn from clinical and non-clinical tests submitted

The Electromagnetic Compatibility and Electrical Safety testing shows that the device is safe to use and meets required standards. The biocompatibility test results show that the Elite iQ handpieces are comprised of safe, biocompatible materials. Performance testing showed no complications from using the recommended settings, thus confirming the treatment parameters set forth in the Hair Removal Treatment Guidance Mode are a safe starting point for practitioners performing test spots.

These non-clinical tests prove the Elite iQ Laser System meets design specifications as well as performance requirements, thus proving the Elite iQ is safe and effective and performs as well or better than the legally marketed predicate device.

Characteristic	Cynosure Elite iQ (KPending)	Cynosure Elite+ (K141425)	Deka Synchro Repla:Y (K150516)	Cynosure Vectus (K120622)
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,	**755 nm:** The Cynosure Elite+ 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 regrowting when measured 6, 9, or 12 months after the completion of a treatment regime. It is used for all skin types (Fitzpatrick I-VI) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles. **1064 nm:** The Cynosure Elite+ Laser is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangectasia, rosacea, venus lake, 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, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic	**755mn 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 regime. On all skin types (Fitzpatrick I - VI) including tanned skin. Treatment of benign pigmented lesions. Treatment of wrinkles. Photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias). **1064nm 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 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.	The Vectus Laser is intended for use in aesthetic, dermatology, general and plastic surgery applications for the treatment of vascular lesions, such as angiomas, hemangiomas, telangiectasia and other benign vascular lesions. Additionally, treatment of leg veins, benign pigmented lesions, hair removal and permanent hair reduction as well as pseudofollilculitis barbae. Treatment for these indications is intended for all Fitzpatrick skin types, including tanned skin. The Skintel Reader is intended as an objective measurement tool for examining skin melanin content for determining and setting a test spot starting fluence. **Note**: For the purposes of this submission, only the Skintel indications are being referenced.

Characteristic	Cynosure Elite iQ (KPending)	Cynosure Elite+ (K141425)	Deka Synchro Repla:Y (K150516)	Cynosure Vectus (K120622)
	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.	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 pseudofolliculitis 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	Coagulation and hemostasis of soft tissue. Benign pigmented lesions such as, but not limited to, lentigos, (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, cloasma. verrucae, skin tags, keratosis and plaques. The laser is indicated for 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. 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. **Pulsed light FT handpiece:** Permanent hair reduction, photocoagulation of vascular lesions, photothermolysis of blood vessels, treatment of benign pigmented lesions.	

Characteristic	Cynosure Elite iQ (KPending)	Cynosure Elite+ (K141425)	Deka Synchro Repla:Y (K150516)	Cynosure Vectus (K120622)
Laser Type	Alexandrite and Nd:YAG laser	Alexandrite and Nd:YAG laser	Alexandrite and Nd:YAG laser	N/A
Wavelength	1064nm (Nd:YAG) and 755nm (Alexandrite)	1064nm (Nd:YAG) and 755nm (Alexandrite)	1064nm (Nd:YAG) and 755nm (Alexandrite)	N/A
Treatment Activation	Footswitch or Fingerswitch	Footswitch or Fingerswitch	Footswitch or Fingerswitch	N/A
Rx/OTC	Prescription	Prescription	Prescription	N/A
Maximum Fluence	600 J/cm²	300 J/cm²	600 J/cm²	N/A
Repetition Rate	0.5 Hz – 10Hz	Up to 3 Hz	0.3 Hz – 10 Hz	N/A
Pulse Duration	0.5ms – 300ms	0.4ms – 300ms	0.2ms – 50ms	N/A
Handpiece (Spot) Size	2.5mm, 5mm, 7mm, 10mm, 12mm, 15mm, 18mm, 20mm, 22mm, & 24mm	3mm, 5mm, 7mm, 10mm, 12mm, 15mm, 18mm, 20mm, 22mm, & 24mm	2.5mm, 5mm, 7mm, 10mm, 12mm, 14mm, 15mm, 16mm, 18mm, 20mm, 22mm, & 24mm	N/A
Patient Contacting Material	**Handpiece Tips:** 316 Stainless Steel	**Handpiece Tips:** 316 Stainless Steel	**Handpiece Tips:** 316 Stainless Steel	N/A
Input Voltage	208-240 V~, 5500 VA, 50-60 Hz, Single Phase	208/230/240 VAC, 30 A, 50/60 Hz, Single phase	230V Single Phase, 50/60Hz	N/A
Max Power Output	4.0 mW	< 5.0 mW	4 mW	N/A
Cold Air Chiller Device Compatible	Yes	Yes	Yes	N/A

Skintel Melanin Reader Specifications

Description	Elite iQ	Vectus
	(KPending)	**(K120622)**
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)