October 20, 2023

Quanta System Spa
Dario Bandiera
Regulatory Affairs Manager
Via Acquedotto, 109
Samarate, VA 21017
Italy

Re: K232236
Trade/Device Name: Echo
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: July 26, 2023
Received: July 27, 2023

Dear Dario Bandiera:

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 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)*
K232236

Device Name
Echo

Indications for Use *(Describe)*
The device is intended to be used in surgical, aesthetic and cosmetic applications in the medical specialties of general and plastic surgery and dermatology, including:
- Treatment of benign vascular lesions
- Hair removal
- Permanent* hair reduction

* permanent hair reduction defined as reduced hair growth with or without maintenance when measured at 6, 9 and 12 months.

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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510(k) Summary

510(K)#	232236
Applicant / Manufacturer and address:	Quanta System S.p.A., Via Acquedotto 109, 21017 Samarate (VA), Italy
Contact person:	Dario Bandiera RA Manager Quanta System S.p.A. Email: dario.bandiera@quantasystem.com Phone: +39-0331-376797
Date Prepared:	10/02/2023
Trade/device name:	Echo
Classification:	Class II
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulation Number:	21 CFR 878.4810
Product Code:	GEX
Predicate devices:	MeDioStar (K192483) and LightSheer Desire (K170179)

1 Device description

The laser device Echo is a 160 W diode laser emitting at 808 nm laser wavelength. The device is a therapeutic and aesthetic medical laser system for professional use only.

For the release of laser radiation to the patient, the device uses, as delivery system, a fiber with a handpiece plugged on its end.

Echo is a transportable mobile electrical equipment with a display with a graphical user interface (GUI) for user-device interaction.

Laser radiation is delivered through optical fibers connected to handpieces having fix spot dimension.

The device is equipped with an integrated skin cooler. In this case, a specific housing called *Skin Cooler* handpiece is provided to provide skin cooling and housing the laser handpiece at the same time.

Laser emission can be activated by the footswitch or by a finger-switch placed on *Skin Cooler* handpieces.

2 Comparison with the predicate

In Table 1, the main specifications of the subject device are summarized and compared to the predicates:

Table 1: Main specifications comparison table.

Specification	Subject device	Predicate 1	Predicate 2	Comments
Device Name	*Echo*	*MeDioStar*	*Lightsheer Desire*	
K number	--	K192483	K170179	--
Manufacturer	Quanta System S.p.A.	Asclepion GmbH	Lumenis	--
Product Code	GEX	GEX	GEX	--
Laser Sources	Diode laser	Diode laser	Diode laser	Same
Laser Wavelengths	808 nm +/- 20 nm	755-950 nm	805-1060 nm	Whitin the range of the predicate devices
Indications for use	Intended for surgical, aesthetic and cosmetic applications in the medical specialties of general and plastic surgery and dermatology. Intended for the treatment of benign vascular lesions. Intended for hair removal and permanent hair reduction.	Intended for surgical, aesthetic and cosmetic applications in the medical specialties of general and plastic surgery and dermatology. Intended for the treatment of benign vascular lesions. Intended for hair removal, permanent hair reduction and the treatment of benign pigmented lesions.	indicated for use in surgical, aesthetic, and cosmetic applications in the medical specialties of general and plastic surgery, and dermatology. The LightSheer Desire System is intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin. The LightSheer Desire System with LightSheer ET/XC 805nm Laser Handpieces are intended for: • Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions and leg veins	Same

Specification	Subject device	Predicate 1	Predicate 2	Comments
Device Name	*Echo*	*MeDioStar*	*Lightsheer Desire*	
			• Treatment of pseudofolliculitis barbae (PFB) • Hair removal, permanent hair reduction* • Treatment of benign pigmented lesions	
Pulse width (max)	5 - 100 ms	3 - 400 ms	Up to 400 ms	Whitin the range of the predicate devices
Fluence (max)	5-90 J/cm2	210 J/cm^2 Max. Fluence Hair reduction 60 J/cm^2	10-100 J/cm2	Same as the predicate device 2
Spot Size	12, 18, 24 mm (round diameter) respective area (cm^2) 1,13 – 2,54 – 4,52	square 10x10, 15x10, 30x10, 31.5x31.5 respective area (cm^2) 1 – 1,5 -3 – 9.9	Square 9x9, 27x9, 22x35 respective area (cm^2) 0.81 – 2.43 – 7.7	Areas within the range of the predicate devices
Repetition Rate (max)	Up to 10 Hz	Up to 20 Hz	Up to 3 Hz	Whitin the range of the predicate device 1
Skin Cooling	Contact skin cooling	contact skin cooling system (metal probe cooled by a peltier element)	Chilltip contact cooling	Same as Predicate devices (contact mode)
Power Supply	Single phase, 100-240V 50-60 Hz	Single phase, 100-240V 50-60 Hz	Single phase, 100-240V 50-60 Hz	Same as predicate devices

3 Indication for use

The device is Intended for surgical, aesthetic and cosmetic applications in the medical specialties of general and plastic surgery and dermatology.
Intended for the treatment of benign vascular lesions.
Intended for hair removal and permanent hair reduction*.

* Permanent hair reduction defined as reduced hair growth with or without maintenance when measured at 6, 9 and 12 months.

4 Non-clinical tests

The present device was subject to non-clinical testing according to the following standards (Table 2):

Table 2: Applied standards.

Standard
IEC 60601-1: 2005/AC 1:2006/A1:2012/AC1:2014/AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014/A1:2020 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: 2010/AMD1: 2013 Collateral standard: Usability
IEC 62366-1: 2015/COR1: 2016 Part 1: Application of usability engineering to medical devices
IEC 62304: 2006/AMD1: 2015 Medical device software (SW)
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
IEC 60825-1: 2014 Safety of laser products – Part 1: Equipment classification and requirements
ISO 10993-1: 2018 Biological evaluation of medical devices

The results of the non-clinical performance standards testing support that the subject device can be used safely and effectively.

5 Substantial equivalence discussion

Echo has the same intended use of the predicate devices and comparable technical specifications.

6 Conclusions

Non-clinical tests conducted support that the device can be used safely and effectively for the proposed indications for use. The differences in technological characteristics between the subject and predicate devices do not raise new questions regarding safety and effectiveness for the proposed indications for use. Thus, the subject device is considered to be substantially equivalent to the predicate devices.