June 4, 2024

Aesthetic Technology Ltd
Martin Hodgson
Head of Regulaton
Unit 211
Europa Boulevard
Warrington, Cheshire WA5 7TN
United Kingdom

Re: K240222
Trade/Device Name: Dermalux Tri-Wave MD MKII (1000021); Dermalux Compact MD (1000024)
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, ILY
Dated: April 23, 2024
Received: April 23, 2024

Dear Martin Hodgson:

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

Digitally signed by Tanisha L. Hithe -S
Date: 2024.06.04 17:25:56 -04'00'

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)*
K240222

Device Name
1. Dermalux Tri-Wave MD MKII
2. Dermalux Compact MD

Indications for Use *(Describe)*
Indications for use include:

• The blue light (415nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

• The red light (633nm wavelength) is generally indicated for treatment of superficial, benign, vascular and pigmented lesions.

• The near-infrared light (830nm wavelength) is generally indicated for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

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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510(k) Summary # K240222

Prepared on: 2024-05-23

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Aesthetic Technology Ltd
Applicant Address	Unit 211 Europa Boulevard Warrington Cheshire WA5 7TN United Kingdom
Applicant Contact Telephone	+44 (0) 1925 396721
Applicant Contact	Mr. Martin Hodgson
Applicant Contact Email	martin.h@dermaluxled.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Dermalux Tri-Wave MD MKII (1000021); Dermalux Compact MD (1000024);
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Powered Laser Surgical Instrument
Regulation Number	878.4810
Product Code	GEX, ILY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product
Code K200659	Dermalux Tri-Wave MD	GEX

Device Description Summary

21 CFR 807.92(a)(4)

The Dermalux Tri-Wave MD MK II & Dermalux Compact MD is a Medical Device (MDR Class IIa, FDA Class II) which emits specific wavelengths of low level, narrow band light for the treatment of certain aesthetic, dermatological and medical indications. The wavelengths used in the Tri-Wave MD MK II & Compact MD systems are Blue 415nm, Red 633nm and Near Infrared 830nm. The Dermalux professional use family consists of the Tri-Wave MD MKII; a floor standing unit with 4 pod treatment head, Compact MD; desk mounted unit with a 3 pod treatment head.

The system enables treatment of the face and the body via an articulated 4 or 3 panel LED head. The panels can be easily adjusted for focused intensity treatments and application to larger body areas.

The system consists of a main body that contains the power supply (100-240Vac, 50/60Hz), power switch, touch screen control panel and a 4 or 3 panel adjustable treatment head that contains Light Emitting Diodes (LEDs).

The power supply is designed to power the internal electronics for the system and the Light Emitting Diodes. The power supply is connected to a suitable mains outlet. The device is switched ON/OFF by a switch located below the screen in the base unit.

The Tri-Wave MD MK II & Compact MD system is operated by a full colour capacitive touch screen which features pre-set and post treatment protocols that can be customised with three power settings. Bespoke protocols can be programmed based on delivered energy or time. The device cannot be networked or connect to the internet, software updates can be performed via a USB flash drive (thumb drive) if required.

The light is generated by Light Emitting Diodes (LED's) which are contained within a treatment head. The treatment head is connected to the main body by articulating arm mechanism. The arm allows the operator to correctly position the LED head over the treatment area.

Protective eye wear is supplied with each Dermalux unit for patient and operator comfort.

The Dermalux systems are not used to make measurements of any sort, or to draw any conclusions regarding the indication to treat. The equipment does not require checks on the light output as the LEDs do not dim with age to any practical extent.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The blue spectrum light (415nm) is intended to treat moderate inflammatory acne vulgaris.

The red spectrum light (633nm) is generally indicated for treatment of superficial, benign, vascular and pigmented lesions.

The near-infrared light (830nm) is generally indicated for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

Indications for Use Comparison 21 CFR 807.92(a)(5)

All devices described in this document have the same indications as those listed in the above section "Intended Use/ Indications for Use" and therefore Aesthetic Technology Ltd consider the Dermalux Tri-Wave MD MKII, and the Dermalux Compact MD to be equivalent to the Dermalux Tri-Wave MD (K200659) for purposes of Section 510(k) of the Federal Food, drug and Cosmetic Act.

Technological Comparison 21 CFR 807.92(a)(6)

Each of the Dermalux devices (Dermalux Tri-Wave MD MKII & Dermalux Compact MD) whether three panels and four panels have the same technological characteristicsand the same indications for use as the Dermalux Tri-Wave MD placed in commercial distribution by Aesthetic Technology Ltd. on May 9, 2020 pursuant to 510(k) premarket notification K200659 and are therefore considered to be substantially equivalent to the Dermalux Tri-Wave MD.

The use of the blue, red and NIR regions of the spectrum are to emit energy to treat the following conditions:

Blue light (415nm wavelength): Treatment of dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

Red light (633nm wavelength): Treatment of superficial, benign, vascular and pigmented lesions.

NIR (830nm wavelength):Temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section.