May 9, 2020

Aesthetic Technology Ltd.
% Richard Hamer
US Agent
Richard Hamer Associates LLC
705 Spring Lakes Blvd
Bradenton, Florida 34210

Re: K200659
Trade/Device Name: Dermalux Tri-Wave MD
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: March 9, 2020
Received: March 12, 2020

Dear Richard Hamer:

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 and Part 809); 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,

Colin Kejing Chen, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200659

Device Name

Derrmalux® Tri-Wave MD

Indications for Use *(Describe)*

The Derrmalux® Tri-Wave MD 's use of the red, blue and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions.

The blue light (4l5nm 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

I. ADMINISTRATIVE

Submitter:
Aesthetic Technology Ltd.
211 Europa Blvd.
Warrington, Cheshire WA5 7TN
United Kingdom
+44 (0) 845 689 1789

Contact Person: Dale Needham

Date of Preparation: May 6, 2020

II. DEVICE NAME

Proprietary Name: Dermalux® Tri-Wave MD

Common Name: Powered Laser Surgical Instrument

Classification Name: Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology

Regulation Number: 21 CFR §878.4810

Regulatory Class: Class II

Product Code: GEX

III. PREDICATE DEVICE

Phototherapy System; K190938; Shanghai Apolo Medical Technology Co, Ltd.

IV. DEVICE DECRIPTION

The Dermalux® Tri-Wave MD is a floor standing Class II medical device which emits specific wavelengths of low level, narrow band light for the treatment of dermatological conditions. The wavelengths used in the Tri-Wave MD system are Blue 415nm, Red 633nm and Near Infrared 830nm.

The device consists of a main body that contains the power supply, power switch, touch screen control panel, and a 4 panel adjustable treatment head that contains Light Emitting Diodes ena-

bling treatment of the face and the body. The panels can be easily adjusted for focused intensity treatments and application to larger body areas.

V. INDICATIONS FOR USE

The Dermalux® Tri-Wave MD's use of the red, blue and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions.

The blue light (4l5nm 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.

VI. COMPARISON TO PREDICATE DEVICE

Parameter	Subject Device	Predicate Device (K190938)
Product name	Dermalux® Tri-Wave MD	Photodynamic Therapy System (HS-770)
Product code	GEX	GEX
Regulation No.	21 CFR 878.4810	21 CFR 878.4810
Class	Class II	Class II
Intended use	Use of the red, blue and near-infrared regions of the spectrum to emit energy to treat dermatological conditions	Use of the red, blue and infrared regions of the spectrum to emit energy to treat dermatological conditions.
Indications for use	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.	The blue light (415nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. The red light (630nm wavelength) is generally indicated for treatment of superficial, benign vascular and pigmented lesions. The infrared light (835nm wavelength) is generally used 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.

Parameter	Subject Device	Predicate Device (K190938)
Power supply	100-240Vac, 50/60Hz, 4.6 -1.85A, 460-430W.	AC 100-240V 50/60Hz 10A
Wavelength	Red light: 633nm±5nm Blue light: 415nm±5nm NIR light: 830nm±5nm	Red light: 630nm±15nm Blue light: 415nm±15nm IR light: 835nm±15nm
Panels Type	4 Panels	• 3 Panel: 180 EA LEDs • 4 Panel: 240 EA LEDs The panels may emit the three lights (red, blue, infrared) individually or in combination
Light frequency	N/A as DC Power	200 Hz
Output Power	Red - 633nm (105mW/cm^2) Blue - 415nm (40mW/cm^2) NIR - 830nm (55mW/cm^2)	Each LED lamp bead has 4 diodes that emit different colors; the energy power of a diode is 3W.
Maximum power density in mW	Red: 105mW/cm^2 Blue: 40mW/cm^2 NIR: 55mW/cm^2	Red light: 115mW/cm^2 Blue light: 120mW/cm^2 IR: 70mW/cm^2 Red/IR: 120mW/cm^2 Blue/IR: 150mW/cm^2
Standard dose in Joules	Red: 126J/cm^2 Blue: 48J/cm^2 NIR: 66J/cm^2	Red: 138J/cm^2 Blue: 144J/cm^2 IR: 84J/cm^2 Red/IR: 144J/cm^2 Blue/IR: 180J/cm^2
Adjustable dose range	Red: 1-126J/cm^2 Blue: 1-48J/cm^2 NIR: 1-66J/cm^2 Red/IR: 1-192J/cm^2 Blue/IR: 1-114J/cm^2 Blue/Red: 1-174J/cm^2	Red: 1-242J/cm^2 Blue: 1-180J/cm^2 IR:1-147J/cm^2 Red/IR: 1-144J/cm^2 Blue/IR:1-180J/cm^2
Treatment area	792cm^2	756cm^2 and 1008cm^2
Treatment time	Up to 20 minutes	20 minutes (recommended treatment time)
Numbers of LEDs	120 LED's per color, per panel. Total of 480 LED's per color per unit. 1440 LED's in total.	3 panels: 180EA 4 panels: 240EA
Working distance	2.5cm minimum distance from source	10~15cm
Operation interface	Display Screen	Display Screen
Dimension	1400mm[H]×500mm[W]×700mm[D]	500mm[H]×500mm[W]×1350mm[D]
Safety classification	Class I	Class I`
Software	Yes	Yes

VII. PERFORMANCE TESTING

Bench: Performance testing of the Dermalux® Tri-Wave MD was conducted to verify that the device met all design specifications. The test results demonstrate that the Dermalux® Tri-Wave MD complies with all requirements, including international and FDA-recognized consensus standards:

EN/IEC 60601-1 (FDA #19-4) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance: 2005

EN/IEC 60601-1-2 (FDA #19-8) Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests: 2018

EN/IEC 62304 (FDA #13-79) Medical device software - Software life cycle processes: 2006

EN/IEC 62471 (FDA #12-249) Photobiological safety of lamps and lamp systems: 2008

IEC 60601-2-57 (FDA #12-242) Medical electrical equipment – Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use: 2011

IEC 62366-1 (FDA #5-113) Medical devices — Part 1: Application of usability engineering to medical devices: 2015

EN/IEC 60601-1-6 (FDA #5-89) Medical electrical equipment -Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability: 2013

Photometric Testing of LED Light Panel

Animal: No studies were performed.

Clinical: No studies were performed.

VIII. CONCLUSION

Based on design considerations and testing of product attributes, we conclude that the Dermalux® Tri-Wave MD performs at least as well as the predicate device. The Dermalux® Tri-Wave MD is therefore considered to be substantially equivalent to the above-mentioned predicate device.