November 18, 2021

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

Re: K212275
Trade/Device Name: Dermalux Flex 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: OHS, OLP, ILY
Dated: October 19, 2021
Received: October 25, 2021

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); 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,

Purva Pandya
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)*
K212275

Device Name

Dermalux Flex MD

Indications for Use *(Describe)*

Intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; 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.
The blue spectrum light is intended to reduce mild to moderate inflammatory acne vulgaris.
Intended to emit energy in the red and infrared spectrum for the use in dermatology for the treatment of periorbital and full face wrinkles.

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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K212275

510(k) SUMMARY

I. ADMINISTRATIVE

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

Contact Person: Dale Needham

Date of Preparation: November 18, 2021

II. DEVICE NAME

Proprietary Name: Dermalux® Flex MD

Common Name: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology

Classification Name: Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based Over-The Counter Wrinkle Reduction (OHS) and Lamp Infrared, Therapeutic Heating (ILY),

Regulation Number: 21 CFR §878.4810

Regulatory Class: Class II

Product Code: OLP, OHS, ILY

III. PREDICATE DEVICES

Dermalux® Flex MD; K202028, Aesthetic Technology Ltd.

Flexible LED Light Therapy Model HK209; K200983, Guangzhou GLOOMED Biological Technology Co. Ltd.

In addition, Omnilux CLEAR; K210948, GlobalMed Technologies and Biophotas Celluma3; K152280, Biophotas, Inc. are cited as reference devices for the purpose of establishing labeling equivalence.

IV. DEVICE DECRIPTION

The Dermalux® Flex MD is a Class II medical device for use on a treatment bed. The device emits specific wavelengths of low level, narrow band light for the treatment of certain dermatological and musculoskeletal indications. The wavelengths used in the Dermalux® Flex MD system are Blue 415nm, Red 633nm and Near Infrared 830nm.

The Dermalux® Flex MD enables treatment of the face and the body via a flexible LED Array. The system is operated by a capacitive touch Controller, which allows one of 3 treatments to be selected through selecting various wavelengths. The light is generated by Light Emitting Diodes (LED's) that are contained within the flexible LED Array. The LED Array can be placed into the Base, holding in the appropriate position to administer a facial treatment. For use on the body, the LED Array is removed from the Base unit and placed over the appropriate body part.

V. INDICATIONS FOR USE

Intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; 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.

The blue spectrum light is intended to reduce mild to moderate inflammatory acne vulgaris.

Intended to emit energy in the red and infrared spectrum for use in dermatology for the treatment of periorbital and full face wrinkles.

VI. COMPARISON TO PREDICATE DEVICES

Parameter	Subject Device	Predicate Device (K202028)	Secondary Predicate (K200983)
Product name	Dermalux® Flex MD Phototherapy System	Dermalux® Flex MD Phototherapy System	Flexible LED Light Therapy Model HK209
Product code	OHS, OLP. ILY	ILY, OHS, OLP	OHS, OLP, ILY
Regulation No.	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810 21 CFR 890.5500
Class	Class II	Class II	Class II
Intended use	Use of the red, blue and near-infrared regions of the spectrum to emit energy to treat dermatological and musculoskeletal conditions.	Use of the red, blue and near-infrared regions of the spectrum to emit energy to treat dermatological and musculoskeletal conditions	Use of the red, blue and near-infrared regions of the spectrum to emit energy to treat dermatological and musculoskeletal conditions
Indications for use	Intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiff-	Intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiff-	The device emitting energy in the blue spectrum is intended to reduce mild to moderate inflammatory acne vulgaris. The device emitting energy in the red and infrared spectrum is intended for the treatment of full-

	ness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. The blue spectrum light is intended to reduce mild to moderate inflammatory acne vulgaris. Intended to emit energy in the red and infrared spectrum for the use in dermatology for the treatment of periorbital and full face wrinkles.	ness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. The blue spectrum light is intended to reduce mild to moderate inflammatory acne vulgaris. Intended to emit energy in the red and infrared spectrum for the use in dermatology for the treatment of periorbital and full face wrinkles.	face wrinkles. The device is Intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; 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
Power supply	100-240Vac, 50/60Hz, 4.6 - 1.85A, 460-430W.	100-240Vac, 50/60Hz, 4.6 - 1.85A, 460-430W.	100-240 Vac 2.0 A, 50/60Hz
Wavelength	Red light: 633nm±5nm Blue light: 415nm±5nm NIR light: 830nm±5nm	Red light: 633nm±5nm Blue light: 415nm±5nm NIR light: 830nm±5nm	Red light: 640nm Blue light: 465nm NIR Light: 880nm
Panels Type	1 Panel	1 Panel	1 Panel
Light frequency	N/A as DC Power	N/A as DC Power	N/A as DC Power
Output Power	Red - 633nm (11.5mW/cm^2) Blue - 415nm (5.52mW/cm^2) NIR - 830nm (5.5mW/cm^2)	Red - 633nm (11.5mW/cm^2) Blue - 415nm (5.52mW/cm^2) NIR - 830nm (5.5mW/cm^2	6.5 mW/cm^2
Standard dose in Joules	Red: 20J/cm^2 Blue: 10J/cm^2 NIR: 10J/cm^2	Red: 20J/cm^2 Blue: 10J/cm^2 NIR: 10J/cm^2	11.7 J/cm^2
Treatment area	Face and Body 792 cm^2	Face and Body 792 cm^2	Face and Body 890 cm^2
Treatment time	Up to 30 minutes	Up to 30 minutes	30 minutes
Treatment protocol (Treatment time)	Acne and Wrinkles: 3-4x weekly; 4 wks. Pain relief: 3x weekly	Not stated	3x weekly; 4wks
Operation interface	Device uses a pre-set timer and software to control treatment duration.	Device uses a pre-set timer and software to control treatment duration.	Not stated
Software	Yes	Yes	Not stated
Use	OTC	Rx	OTC

Substantial equivalence is readily evidenced by comparison of product attributes summarized in the table above. Apparent differences in output power and standard dose do not impact safety or effectiveness because the amount of energy delivered to the skin is similar due to differences in treatment duration and distance from the LED source.

VII. PERFORMANCE TESTING

Bench: Performance testing of the Dermalux® Flex MD was conducted to verify that the device met all design specifications. The test results demonstrate that the Dermalux® Flex 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 60601-1-11 (FDA #19-14) Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment: 2015

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

ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

Animal: No studies were performed.

Clinical: No studies were performed.

VIII. CONCLUSION

The Dermalux Flex MD is technologically identical to the predicate device cleared under K202028, intended for over-the-counter use, and similar to secondary predicate device K200983. Labeling is equivalent to reference devices K210948 and K152280. Based on design considerations and testing of product attributes, we conclude that the Dermalux® Flex MD performs at least as well as the predicate devices. The Dermalux® Flex MD is therefore considered to be substantially equivalent to the above-mentioned predicate devices.