May 20, 2022

Marci Beauty Inc
℅ Helen Nan
General Manager
Wenzhou Cytech Information Service Co., Ltd.
Room302, Building 3, Hangqian Mansion, Hanqian Street,
Lucheng District
Wenzhou, Zhejiang 325000
China

Re: K210545
Trade/Device Name: Infrared Red Blue LED Light Heat Beauty Machine
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: OLP, OHS
Dated: October 13, 2020
Received: February 25, 2021

Dear Helen Nan:

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)*
K210545

Device Name
Infrared Red Blue LED Light Heat Beauty Machine

Indications for Use *(Describe)*
The Infrared Red Blue LED Light Heat Beauty Machine is an hand-held over-the-counter phototherapy device, the red and infrared light is intended for the use in treating wrinkles on the face and the blue light is intended for the treatment of the mild to moderate inflammatory acne.
This device is indicated for adults only.

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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K210545 510(k) Summary

1.0 Submitter Information

Company:	Marci Beauty Inc
Address:	4290 Cameron st, Unit 7, Paradise NV 89103, U.S.
Phone:	086-180-26309981
Contact Person:	Shaul Rappaport
E-mail:	service@spacetouch.com

2.0 Device Information

Trade/Device Name:	Infrared Red Blue LED Light Heat Beauty Machine
Model:	Vega; Jupiter; Neptune
Regulation Description:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Device:	Light Based Over The Counter Wrinkle Reduction; Over-The-Counter Powered Light Based Laser For Acne
Common Name:	Acne and Wrinkle Light Therapy System
Product Code:	OLP, OHS
Review Panel:	General & Plastic Surgery
Submission Type:	510(k)
Regulation Number:	21 CFR 878.4810
Device Class:	Class II

3.0 Predicate Device Information

Device Name	510K Number	Submitter
Aduro Light Therapy Handheld	K203271	Shenzhen Kaiyan Medical CO LTD
LED FACIAL LIGHT THERAPY MASK (Model: HK207)	K200983	Ningbo Hesi Electric Co., Ltd
Elevare Plus	K172909	Omm Imports d/b/a Zero Gravity
Sapphire, Elevare Sapphire	K172555	Omm Imports, Inc. d/b/a Zero Gravity

4.0 Device Description

The proposed device Infrared Red Blue LED Light Heat Beauty Machine, is a over-the-counter device hat uses low power light spectrum at red blue and infrared LED, at wavelength of 625±5nm, 465nm, 850±5nm emitting optical power in a uniform distribution.

The device is composed of a handpiece for delivery of light energy, base unit for charging and storage when not in use, and A.C.charging adapter. It is a hand-held light emitting diode (LED) device for treatment of wrinkles on face and mild to moderate inflammatory acne designed for home use.

5.0 Indications for Use

The Infrared Red Blue LED Light Heat Beauty Machine is an hand-held over-the-counter phototherapy device, the red and infrared light is intended for the use in treating wrinkles on the face and the blue light is intended for the treatment of the mild to moderate inflammatory acne.

This device is indicated for adults only.

6.0 Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device conforms to the following standards:

Standard	Title
IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
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 60601-1-11	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
IEC 60601-2-57	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
IEC 62471	Photobiological safety of lamps and lamp systems
ISO 14971	Application of risk management to medical devices
ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

7.0 Clinical Test Conclusion

Clinical data was not including in this submission.

8.0 Substantial Equivalence

The Infrared Red Blue LED Light Heat Beauty Machine is substantially equivalent with the legally marketed device. The Infrared Red Blue LED Light Heat Beauty Machine have been tested for biocompatibility, electromagnetic compatibility, electrical safety, and other physical performance as documented above and meet or exceed the applicable requirements of the recognized and other related standards and therefore the proposed product is as safe and as effective for it's intended use.

The table below shows similarities and differences between the predicate device and the subject device.

Table 1 -General Comparison

Device	Subject Device	Predicate Device #1	Predicate Device #2	Predicate Device #3	Predicate Device #4
Name	Infrared Red Blue LE D Light Heat Beauty Machine	Aduro light therapy Handheld	The LED FACIAL LIGHT THERAPY MASK	Elevare Plus	SAPPHIRE
510k number	K210545	K203271	K200983	K172909	K172555
Classification	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Product code	OHS,OLP	OHS,OLP	OHS,OLP	OHS	OLP
Use	OTC	OTC	OTC	OTC	OTC
Model	Vega; Jupiter; Neptune	HD-03A	HK207	-	-
Indication for Use	The Infrared Red Blue LED Light Heat Beauty Machine is an hand-held over-the-counter phototherapy device, the red and infrared light is intended for the use in treating wrinkles on the face and the	The Aduro light therapy Handheld (Model: HD-03A), the red light is intended for the treatment of periorbital wrinkles, and the blue light is intended for the treatment of the mild to moderate	The LED FACIAL LIGHT THERAPY MASK is intended to: - The device emitting energy in the blue is intended to reduce the mild to moderate inflammatory acne vulgaris. - The device emitting	The Elevare Plus is an Over-the-Counter (OTC) device intended for the use in treating wrinkles on the face.	The SAPPHIRE is an over – the -counter hand held, battery operated, light therapy device that uses light emitting diodes (LEDs) that emit a specific wavelength of 415nm (Blue Light) that is intended for use

	blue light is intended for the treatment of the mild to moderate inflammatory acne. This device is indicated for adults only.	inflammatory acne.	energy in the red and infrared spectrum is intended for the treatment of full-face wrinkles.		in the treatment of mild to moderate inflammatory acne.
Anatomical Sites	Entire Face	Entire Face	Entire Face and Body	Entire Face	Entire Face
Design	Hand-held Type	Hand-held Type	Face-wear Type	Hand-held device	Hand-held device
Target Population	Adult with wrinkles on face; Adult with mild to moderate inflammatory acne	Individuals with periorbital wrinkles on face, Individuals with mild to moderate inflammatory acne	Adult with wrinkles on face; Adult with mild to moderate inflammatory acne	Individuals with wrinkles on face	Adult with mild to moderate inflammatory acne
The distance between the LEDs to treatment surface	2 - 3 cm	Does not directly contact the patient; approximately 2-6 inches	0.5 - 3 cm	Direct contact	Direct contact
Treatment regimen	3 times a week for 30 min. 4 weeks	3-5 minutes on each treatment area. For best results 3-5 times per week with 2 day rest.	3 times a week for 30 min. 4 weeks	3 minutes daily, 5 days per week for 8 weeks	4 minutes per area, twice per week for 4 weeks (total of 8 treatments)

Table 2 - Performance Comparison

Device	Subject Device	Predicate Device #1	Predicate Device #2	Predicate Device #3	Predicate Device #4
Wavelengths	Blue: 465nm Red: 620-630nm IR: 845-855nm	Blue: 415±10nm Red: 630±10nm IR: 850nm	Blue: 465nm Red: 640nm IR: 880nm	Red: 610nm, 630nm, 660nm IR: 850±5nm	Blue: 415±5nm
Main Unit Weight	265g	135g±2g	Not publicly available	150g	Not publicly available
Housing Materials of main unit	ABS Plastic and Aluminum Head	ABS Plastic	biocompatible material	GLASS PROBE (HEAD)	GLASS PROBE (HEAD)
Power Supply	900mAh, Rechargeable Li-Ion batteries	2600mAh, 3.7V Li battery	Input: 100 – 240Vac, 2.0 A, 50/60Hz	2 Li-Ion rechargeable batteries	rechargeable Li-Ion batteries
Electrical power	100~240V AC 50/60HZ 0.5A	Not publicly available	Input: 100 – 240Vac, 2.0 A, 50/60Hz	100~240V AC 50/60HZ 0.35A	100~240V AC 50/60HZ 0.7A
Energy Source	24 LEDs	Not publicly available	Not publicly available	25 LEDs	Not publicly available
Intensity (mW/cm^2)	Blue Light Mode: 5.4 Red Light Mode: 7.2	Blue: 20-65 Red: 40-80	6.5	65±5	50
Software	Yes	Yes	Yes	Yes	Yes
Automatic Shut Off	Yes 8 Minutes	Yes 3 Minutes	Not publicly available	Yes	Yes
Temperature stabilizer	40±2℃	Not publicly available	Not publicly available	41±2℃	40-42℃

Table 3-Safety Comparison

Device	Subject Device	Predicate Device #1	Predicate Device #2	Predicate Device #3	Predicate Device #4
Electric Safety	Comply with IEC 60601-1, IEC 60601-1-11	Not publicly available	Comply with IEC 60601-1, IEC 60601-1-11	Comply with IEC 60601-1, IEC 60601-1-11	Comply with IEC 60601-1, IEC 60601-1-11
Photobiological Safety	Comply with IEC 62471	Not publicly available	Not publicly available	Comply with IEC 62471	Comply with IEC 62471
EMC	Comply with IEC 60601-1-2	Not publicly available	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2
Bioconpatibility	Comply with ISO 10993-1, ISO 10993-5 and ISO 10993-10	Comply with ISO 10993-1, ISO 10993-5 and ISO 10993-10	Comply with ISO 10993-1, ISO 10993-5 and ISO 10993-10	Comply with ISO 10993-1, ISO 10993-5 and ISO 10993-10	Comply with ISO 10993-1, ISO 10993-5 and ISO 10993-10

9.0 Conclusion

Taking into consideration the table for substantial equivalence, an analysis of safety, indications, intended uses, performance, and technological properties, the proposed device raises no new issues of safety or effectiveness and has been found to be substantially equivalent to the predicate device.