December 21, 2021

Theragun, Inc.
% Thomas Padula
Vice President Regulatory Compliance
Schiff & Company, Inc.
583 Mountain Avenue
North Caldwell, New Jersey 07006

Re: K212155
Trade/Device Name: TheraFace LED
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, IRO
Dated: July 7, 2021
Received: July 12, 2021

Dear Thomas Padula:

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)*
K212155

Device Name
TheraFace LED

Indications for Use *(Describe)*
The device can work in multiple function modes as following with different indication for use:
1）The red light is intended to treat periorbital wrinkles.
2）The blue light is intended to treat mild to moderate inflammatory acne.
3）The Red + IR is intended to treat periorbital 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K212155 (as required by 807.92)

(1) SUBMITTER:

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Date prepared: December 16, 2021

Application Correspondent:

Contact Person: Thomas Padula
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(2) DEVICE NAME:

Trade Name: TheraFace LED
Common Name: Light Emitting Diode (LED) Device
Classification Name: Light Based Over the Counter Wrinkle Reduction, over-the counter powered light-based laser for acne
Device Classification: Class II
Review Panel: General & Plastic Surgery
Regulation Number: 21 CFR 878.4810, 890.5975
Product Code: OHS, OLP

(3) PREDICATE DEVICE(S): Substantial equivalence is based on following legally marketed devices.

Sponsor	Heat In A Click	Zhongshan Bisen Plastic Electronic Products Co., Ltd.
Device Name and Model	2 Face / Face Evolution	RED Light Device
510(k) Number	K171821 (Primary Predicate)	K162489
Product Code	OHS, OLP	OHS
Regulation Number	878.4810	878.4810
Regulation Class	II	II

(4) DESCRIPTION OF THE DEVICE:

The TheraFace LED device is a lightweight device which uses specified wavelengths of LED light. For LED light irradiation function, the device produces light in the red light region of the spectrum (633±10nm), combination of IR and Red light (830nm±10nm&633 ± 10 nm), or in the blue light region of the spectrum(415±10nm).

The TheraFace LED device consists of a main control unit and its attachment applicators for the LED irradiation ring, which can be controlled by the device control button. The device is powered by one internal lithium rechargeable battery which can be charged by an external battery charger.

Red light mode: In Red light irradiation mode, the device utilizes Light Emitting Diodes to emit red light. The output is adjustable to one wavelength with a narrow spectral bandwidth in 633±10nm. It provides narrow bands of red-light energy and is intended to treat periorbital wrinkles.

Blue light mode: In blue light irradiation mode, the device utilizes Light Emitting Diodes to emit blue light. The output is adjustable to one wavelength with a narrow spectral bandwidth in 415 ±10nm. It provides narrow bands of blue light energy to facial skin, and is intended to treat mild to moderate inflammatory acne.

Red+ IR mode: When the device is operated in the red combined with infrared light mode, it emits LED light in the RED (633 nm) and IR (830 nm) spectrum on facial skin. It is intended to treat periorbital wrinkles.

(5) INDICATIONS FOR USE:

The device can work in multiple function modes as following with different indication for use:

1）The red light is intended to treat periorbital wrinkles.

2）The blue light is intended to treat mild to moderate inflammatory acne.

3）The Red + IR is intended to treat periorbital wrinkles.

(6) COMPARISON WITH PREDICATE DEVICES: The following table is a comparison of TheraFace led and predicate devices.

TheraFace LED is substantially equivalent in terms of the technological characteristics, features, specifications, materials, mode of operation and indications for use, to 2 Face / Face Evolution - K171821 **(Primary Predicate)**, RED Light Device K162489, cleared for marketing under 510(K).

Elements of Comparison	Subject Device	Primary Predicate Device	Supplement Predicate Device 1	Remark
Basic Unit Characteristics				
Device Name and Model	*TheraFace LED*	2 Face / Face Evolution	RED Light Device BZ-0606	--
510 (K) Number	Applying	K171821	K162489	--
Product Code	OHS, OLP	OHS, OLP	OHS	See Note A above
Regulation Number	878.4810	878.4810	878.4810	See Note A above
Intended Use	1） The red light is intended to treat periorbital wrinkles. 2） The blue light is intended to treat mild to moderate inflammatory acne. 3) The Red + IR is intended to treat periorbital wrinkles.	2 Face / Face Evolution is a hand-held device for over the counter aesthetic purposes. The Photon mode: 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 inflammatory acne.	The RED Light Device is an OTC device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.	SE Note 1 Only compared with its LED photon mode with K171821.
Apply parts	Face	Face	Face	SE
Power Sources	Lithium battery :2x3.7V	DC 3.7V 2200mAh	Adaptor:100~240V AC 50/60Hz Lithium battery: 2x3.7V	SE
Method of Line Current Isolation	Battery Supply	Battery Supply	Battery Supply	SE
Indicator Displ — On/Off Status	Yes	Yes	--	SE

Elements of Comparison		Subject Device	Primary Predicate Device	Supplement Predicate Device 1	Remark
ay	Low Battery	Yes	Yes	--	SE
	Voltage/Current Level	Yes	Yes	--	SE
Time Range		Red light: 5 - 7 minutes per treatment zone Blue: 5 - 7 minutes per treatment zone Red+IR: 5 - 7 minutes per treatment zone	Photon Mode (5~7 minutes)	Red+IR: For the first month (4 weeks), treatment should be performed 3 times a week for 15-20 minutes each time (5-7 minutes on each treatment zone).	SE
Console weight		230g	200g	--	SE Note 2
LED wavelength		Red light: 633nm±10nm Blue light: 415nm±10nm Red+IR: 633±10nm / 830nm±10nm	Red Light (630nm±3nm Wavelength), Blue Light (415nm±3nm Wavelength)	Red: 633 ±5nm Infrared: 830 ±5nm	SE Note 3
LED Power Density		Red light 73±5 mW/cm^2 Blue light 64±5 mW/cm^2 Red+IR: 73±5/55±5 mW/cm^2	Red light: 73.26 mW/cm^2±10% Blue light: 64.10mW/cm^2±10%	Red+Infrared combined light irradiation: 125 mW/cm^2 70mW/cm^2(633 nm); 55 mW/cm^2 (830 nm)	SE Note 3
Material of device and construction		PC Plastic & Stainless Steel	ABS Plastic & Stainless Steel	ABS & Stainless Steel	SE Note 4

Elements of Comparison	Subject Device	Primary Predicate Device	Supplement Predicate Device 1	Remark
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5, ISO10993-10.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	SE
Electrical and Photo Safety	Comply with IEC 60601-1, IEC 60601-1-11 IEC 60601-2-57 IEC 62471	Comply with IEC 60601-1 IEC 60601-1-11 IEC60601-2-57	Comply with IEC 60601-1 IEC 60601-1-11 IEC 60601-2-57 IEC 62471	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE

Comparison in Detail(s):

Note 1:

For red light irradiation mode and blue light irradiation mode, the subject device can be substantially equivalent to predicate device K171821, which was defined as primary predicate device.

For Red light combined with Infrared light, it can be substantially equivalent to predicate device K162489.

Note 2:

Even though there is a console weight difference between the subject device and predicate devices; they all are portable medical devices and comply with IEC60601-1 testing. Therefore, such a minor difference would not affect safety and effectiveness.

Note 3 (LED Wavelengths; Power density):

For LED wavelength:

Although there is a Minor difference of the LED wavelengths between the subject and predicate devices due to deviation tolerance of LED wavelength, they all belong to the range of red, blue and infrared light wavelengths, and the device passed the testing according to IEC60601-2-57, so such minor difference on wavelength would not affect safety or effectiveness.

For LED Power density:

There is only minor difference of the power density between the subject and predicate devices; and the device passed the testing according to IEC60601-2-57, so such a minor deviation would not affect safety and effectiveness.

Note 4

Even though there is a difference for the material between the subject device and the predicate device, its material complies with ISO10993-5 and ISO10993-10.

(7) PERFORMANCE STANDARDS APPLIED:

A series of studies were completed to demonstrate the substantial equivalence of TheraFace LED to the predicate device. All testing was conducted in accordance with and in conformance to applicable device regulations and guidance. Results of all testing demonstrate the device is non-toxic, is comparable to other currently marketed devices and is substantially equivalent to legally marketed predicates and included:

Biocompatibility

ISO 10993-5:2009, biological evaluation of medical devices – part 5: tests for in vitro cytotoxicity. (Biocompatibility).

ISO 10993-10 :2010, biological evaluation of medical devices - part 10: tests for irritation and skin sensitization. (Biocompatibility).

Electrical Safety and Electromagnetic Compatibility

IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC / EN 60601-1-2: 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic Compatibility.

IEC 60601-1-11 :2015, 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 health care environment.

IEC 60601-2-57: 2011 for use in conjunction with IEC 60601-1:2005, Medical electrical equipment – Part 2: 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 62471:2006, Photobiological safety of lamps and lamp systems.

AAMI TIR69:2017, ANSI C63.27-2017 Wireless Coexistence Test

(8) PERFORMANCE TESTING BENCH

The following performance bench testing was conducted:
Usability Study Report, TheraFace LED
Light Power Density Test Report

(9) PERFORMANCE TESTING CLINICAL

There were no clinical studies performed.

(10) CONCLUSION: TheraFace LED has the same indications for use and technology characteristics as the predicate devices. TheraFace LED is as safe, as effective, and performs as well as the predicate devices.