September 29, 2021

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

Re: K212238
Trade/Device Name: TheraFace microcurrent
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: July 15, 2021
Received: July 19, 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,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K212238

Device Name
TheraFace microcurrent

Indications for Use *(Describe)*
The TheraFace microcurrent is a hand-held device for over-the-counter aesthetic purposes . The TheraFace microcurrent is indicated for facial stimulation.

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 (as required by 807.92)

(1) SUBMITTER:

THERAGUN, Inc.
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Registration Number: 3012386142
FEI Number: 3012386142
Contact person: CJ Frederick – Director, Regulatory Compliance
Telephone: 310-570-8341
Email: jaime@therabodycorp.com
Date prepared: September 20, 2021

Application Correspondent:
Contact Person: Thomas Padula
Company: Schiff & Company, Inc.
Address: 583 Mountain Avenue, North Caldwell, NJ 07006
Tel: 201-317-8810
Email: thomaspadula@schiffandcompany.com

(2) DEVICE NAME:

Trade Name: TheraFace microcurrent
Common Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Classification Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Device Classification: Class II
Review Panel: Neurology; General & Plastic Surgery
Regulation Number: 21 CFR 882.5890
Product Code: NFO

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

Sponsor	Heat In A Click
Device Name and Model	2 Face / Face Evolution
510(k) Number	K171821
Product Code	NFO
Regulation Number	882.5890
Regulation Class	II

(4) DESCRIPTION OF THE DEVICE:

The TheraFace microcurrent device consist of main control unit and its attachment applicators for micro-current output which can be control by the device control button or APP in cell phone via Bluetooth

connection. The device powered by one internal lithium rechargeable battery which can be charged by external battery charger.

The device has the electrode contractors for facial stimulation by applying an electrical micro current to face skin. The output waveform is formed of regulated Voltage of Biphasic pulse and provided with 3 levels of output intensity, which can be adjusted by user. The low-level electrical current pulse goes through the face muscle and cause face muscle contraction and relaxation for facial stimulation.

(5) INDICATIONS FOR USE:

The TheraFace microcurrent is a hand-held device for over-the-counter aesthetic purposes. The TheraFace microcurrent is indicated for facial stimulation.

(6) COMPARISON WITH PREDICATE DEVICES:

Following table is a comparison of TheraFace microcurrent and predicate devices.

TheraFace microcurrent 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, cleared for marketing under 510(K).

Elements of Comparison	**Subject Device**	**Primary Predicate Device**	**Remark**
Basic specification			
Device Name and Model	*TheraFace microcurrent*	2 Face / Face Evolution	--
510 (K) Number	Applying	K171821	--
Product Code	NFO	NFO	--
Regulation Number	882.5890	882.5890	--

Intended Use	The TheraFace microcurrent is a hand-held device for over-the-counter aesthetic purpose. The TheraFace microcurrent is indicated for facial stimulation.	2 Face / Face Evolution is a hand-held device for over the counter aesthetic purposes. (1) The EMS mode is indicated for facial stimulation. (2) 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.	SE Note 1 (Only compared with its EMS function of K171821)
Apply parts	Face	Face	SE
Power Sources	Lithium battery :2x3.7V	DC 3.7V 2200mAh	SE
Method of Line Current Isolation	Battery Supply	Battery Supply	SE
Number of Modes for Micro current stimulation	1	1	SE
Number of Channels for Micro current stimulation	1	1	SE
Synchronous or Alternating	N/A	N/A	SE
Regulated Current or Regulated Voltage	Both	Both	SE
Software/Firmware/ Microprocessor control	Yes	Yes	SE
Automatic Overload Trip	Yes	Yes	SE

Automatic No-load Trip		Yes.	Yes	SE
Automatic Shut Off		Yes.	Yes	SE
Patient Override Control		Yes	Yes	SE
Indicator Display	On/Off Status	Yes	Yes	SE
	Low Battery	Yes	Yes	SE
	Voltage/ Current Level	Yes	Yes	SE
Time Range		Micro current 5 minutes	EMS Mode (5 minutes) Photon Mode (5~7 minutes)	SE
Console weight		230g	200g	SE Note 2
Waveform		Pulsed Biphasic	Pulsed Biphasic,	SE
Shape		Rectangular	Rectangular	SE
Maximum Output Voltage (+/- 10%)		0.24V @ 500Ω 1.0V @ 2kΩ 5.0V @ 10kΩ	0.31V @ 500Ω 1.16V @ 2kΩ 5.56V @ 10kΩ	SE Note 3

Maximum output Current	500 µA @ 500 Ohm 500 µA @ 2k Ohm 500 µA @ 10k Ohm	620µA @ 500Ω 580µA @ 2kΩ 556µA @ 10kΩ	SE Note 3
Frequency range	8.3 Hz	8.33 Hz	SE
Pulse width range	60ms	60ms	SE
Net Charge	0 µC @ 500Ω	0 µC @500 Ω	SE
Max Phase charge	29.4µC@ 500 Ohm	26.3µC@ 500 Ohm	SE Note 4
Maximum Current Density	0.2mA/cm² @500Ω	0.33 mA/cm²@ 500Ω	SE Note 5
Maximum Power Density	23.1µW/cm² @500Ω	4.34 µW/cm² @ 500Ω	SE Note 5
ON time	60 ms	60 ms	SE
OFF time	60 ms	60 ms	SE
Contraction and Relaxation time	60 ms ON/OFF	60 ms ON/OFF	SE

Material of device and construction	PC Plastic & Stainless Steel	ABS Plastic & Stainless Steel	SE Note 6
Bio-compatibility	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.	SE
Electrical Safety	Comply with IEC 60601-1 IEC 60601-1-11 IEC 60601-2-10	Comply with: IEC 60601-1 IEC 60601-1-11 IEC 60601-2-10	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE

Comparison in Detail(s):

Note 1:

There is multiple function operation mode in the predicate device, the subject device TheraFace microcurrent only has one micro-current operation mode. To this microcurrent mode, the subject device can be substantial equivalent to predicate device K171821.

Note 2:

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

Note 3:(Maximum Output Voltage and Maximum Output Current):

The effect of micro current stimulation is determined by micro current output waveform and output current.

There is only minor difference about the output voltage and current between the subject device and the predicated devices, it can still obtain the same effect because our output voltage and output current are in the range which is between the value of K171821. Also, the subject device complies with IEC 60601-1, and IEC60601-2-10 which means we have proved its safety as well as the effectiveness comparing with the predicate devices. Therefore, the subject device and predicate devices are substantially

equivalence on output voltage and current.

Note 4: (Max phase charge)

Even there is minor difference on the max phase charge between subject device and predicate device, but the pulse waveform is Pulsed Biphasic, and its net charge is 0 μC;

And the micro current waveform parameters comply with IEC60601-2-10, so the difference on max phase charge would not raise safety issue; and it would not affect effectiveness for facial stimulation.

Therefore, such minor difference would not affect safety and effectiveness issue.

Note 5 (Maximum current density and Maximum power density):

The effect of micro current stimulation on facial skin are determined by micro-current output waveform and output current. The maximum current density and power density is the parameters related to safety of medical device.

For maximum current density, there is only little difference on it between the subject device and the predicated device K171821, it is little smaller than the value of K171821, so it would not raise safety issue. And viewing from max current density value in the predicate device K171821, the value of subject device is in the range of max current density between predicate device K171821. Therefore, such minor difference would not affect safety and effectiveness issue.

For maximum power density, the value of maximum power density of subject device is larger than the predicate device. But the maximum power density meets with the maximum allowed value 0.25 (W/cm^2) required in FDA guidance. Also, the subject device complies with IEC 60601-1, and IEC60601-2-10 which means we have proved its safety as well as the effectiveness comparing with the predicate devices.

Therefore, such minor difference would not affect safety and effectiveness issue.

Note 6

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

Finial Conclusion:

The TheraFace microcurrent device has the same indications use and technology characteristics as the predicate devices. TheraFace microcurrent device is as safe, as effective, and performs as well as the predicate devices.

(7) PERFORMANCE STSTANDARDS APPLIED:

A series of studies were completed to demonstrate the substantial equivalence of TheraFace microcurrent to the predicate devices. 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 60601-2-10: 2012, Medical electrical equipment -- Part 2: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.

TheraFace Micro-current Test Report, Theragun study TG-TheraFace-1010

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

Usability Engineering

Usability Study Report, Theragun study TG-Theraface microcurrent-013

(8) CONCLUSION:

TheraFace microcurrent has the same indications for use and technology characteristics as the predicate devices. TheraFace microcurrent is as safe, as effective, and performs as well as the predicate device.