June 9, 2023

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

Re: K230293
Trade/Device Name: TheraFace Mask
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
Dated: May 10, 2023
Received: May 10, 2023

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,

Jianting Wang -S

Jianting Wang
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230293

Device Name

TheraFace Mask

Indications for Use *(Describe)*

- Red Light is intended to treat full face wrinkles
- Blue Light is intended to treat mild to moderate inflammatory acne
- Red + Infrared Light is intended to treat 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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510(k) Summary (as required by 807.92)

K230293

Date: June 6, 2023

(1) SUBMITTER:

THERABODY, Inc.
6100 Wilshire Blvd Suite 200
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Registration Number: 3012386142
FEI Number: 3012386142
Contact person: CJ Frederick, III
Telephone: 484-888-1290
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Date prepared: May 18, 2023

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

(2) DEVICE NAME:

Trade Name: TheraFace Mask
Common Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name: Light Based Over the Counter Wrinkle Reduction
Device Classification: Class II
Review Panel: General & Plastic Surgery
Regulation Number: 21 CFR 878.4810
Product Code: OHS, OLP

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

Device Name and Model	MZ Skin LightMAX Supercharged LED Mask 2.0	LED Therapy Device	RED Light Device
510(k) Number	K213184 (Primary Predicate device)	K192295 (Predicate device)	K162489 (Reference device)
Product Code	OHS, OLP	OHS, OLP	OHS
Regulation Number	878.4810	878.4810	878.4810
Regulation Class	II	II	II

(4) DESCRIPTION OF THE DEVICE:

The TheraFace Mask 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 Mask device is shaped like a human face and is designed to be "one size fits most." There are two physical buttons located on the mask; one controls the LED function and the other controls the vibration function. The 648 LEDs in the device are powered by two internal lithium-ion rechargeable batteries which are charged via USB Type C or A cable with power adaptor.

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

Blue light mode: In blue light irradiation mode, the device utilizes Light Emitting Diodes to emit blue light. The output is 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±10nm) and IR (830 nm±10nm) spectrum on facial skin. It is intended to treat full face wrinkles.

Vibration mode: The device can drive 8 vibration motors around the eyes and 9 vibration motors on the top and back of the head in different vibration speeds. There are 3 different vibration patterns; continuous mode, breathe mode, and wave mode. Vibration is included for general relaxation purposes.

(5) INDICATIONS FOR USE:

The device can work in multiple modes as described below, with the corresponding indications for use:

- Red Light is intended to treat full face wrinkles
- Blue Light is intended to treat mild to moderate inflammatory acne
- Red + Infrared Light is intended to treat full face wrinkles

(6) COMPARISON WITH PREDICATE DEVICES: Following table is a comparison of TheraFace Mask and predicate/reference devices.

TheraFace Mask is substantially equivalent in terms of the technological characteristics,

features, specifications, materials, mode of operation and indications for use, to MZ Skin LightMAX Supercharged LED Mask 2.0 K213184 (Primary Predicate Device), LED Therapy Device, K192295 (Secondary Predicate device), and RED Light Device K162489 (Reference device), cleared for marketing under 510(K).

Comparison in Detail(s):

Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	Proposed Device	Primary Predicate Device K213184	Secondary Predicate Device K192295	Reference Device K162489	Remark
Product Code	OLP, OHS	OLP, OHS	OHS, OLP	OHS	*(Please provide Justification for differences)*
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	Class 2	Class 2	Class 2	Class 2	SAME
Indication for Use	●Red Light is intended to treat full face wrinkles ●Blue Light is intended to treat mild to moderate inflammatory acne ●Red + Infrared Light is intended to treat full face wrinkles	The MZ Skin LightMAX Supercharged LED Mask 2.0 is an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris of the face. The MZ Skin LightMAX Supercharged LED Mask 2.0 is an over-the-counter device intended to emit energy in the red and Near Infra-red spectrum and is intended for the use in the treatment of full-face wrinkles.	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 device is indicated for adults only.	The RED Light Device is an OTC device indicated to emit energy in the red and IR region of the spectrum for use in the dermatology for the treatment of periorbital wrinkles.	*No differences in Indications for Use for Red Light, Blue Light or Red Light + Near Infra-Red Light. Of note is that while the primary predicate uses the term "acne vulgaris," this is a form of inflammatory acne and therefore the IFU for blue light are identical for all devices.*

Prescription/OTC	OTC	OTC	OTC	OTC	SAME

Table 2 Performance Comparison

Item	Proposed Device	Primary Predicate Device K213184	Secondary Predicate Device K192295	Reference Device K162489	Remark
Power Source	5-15V DC 2.5A max powered by 2 Li-Ion Batteries 3.7V 1500mAh) is charged via Universal USB charger cord or fast charger adaptor	Lithium-ion battery powered controller. Power Supply charges the batter by direct plug-in adapter (2 or 3 pin input socket and wall plug. Power cable is connected to the controller by a standard micro-USB A-C Connector.	5.V DC 2.0 A Powered by direct plug-in adapter: Input 100-240V AC, 50/60 Hz, 0.5A Max., Output 5.0V DC 2.0A	Adaptor: 100~240V AC 50/60Hz Lithium Battery: 2 x 3.7V	Note 1
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Yes	SAME
Power (mW/cm^2)	Red: 73 ±5mW/cm^2 Blue: 64 ±5mW/cm^2 Red+IR: 73 ±5mW/cm^2 / 55 ±5mW/cm^2	Blue/Red: 44mW/cm^2 Red/NIR: 29mW/cm^2	Red light: 80 ±10% Blue light: 50 ±10%	125mW/cm^2 70mW/cm^2 (633nm); 55 mW/cm^2 (830nm)	Reference device has the same/similar power density as proposed device and has been cleared therefore proposed device is safe and effective.
Dose (J/cm^2)	Red 13.14 +/- 0.9 J/cm^2 Blue: 11.52 +/- 0.9 J/cm^2 Red+IR: 11.52 +/- 0.9 J/cm^2	Red 9.6J/cm^2 & 11J/cm^2 Blue: 16.8J/cm^2 NIR: 7J/cm^2	Not available	Not available	
Wavelength	Red: 633 ±10nm Blue: 415 ±10nm Red+IR:633nm ±10nm/830 ± 10 nm	Blue light: 415nm ±10nm Red light: 630nm ±10nm NIR: 830±10nm	Blue light: 415nm ±5nm Red light: 630nm ±5nm	Red: 633 +5nm IR: 830 +5nm	Note 2 SAME for Blue Light & Red+IR (aka IR or NIR) Light

Treatment Duration	LED: 3 minutes each light mode for a total of 9 minutes per treatment, recommended to use 2 to 5 times per week. Vibration: accompanies LED treatments or can be used without LED's active. 3 vibration patterns, 5 minutes each, for a total of 15 minutes. During blue light treatment mode, vibration is not active around the eyes. Vibration is included for a more relaxing experience.	10 minutes per treatment. Acne: 4x Weekly, 6 weeks Wrinkles: 5x Weekly, 6 weeks	3-5 minutes each time, twice a week	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).	Note 3
Main Materials	PC+ABS	Silicone	PC+ABS	ABS + Stainless Steel	SAME and Similar

Table 3 Safety Comparison

Item	Proposed Device	Primary Predicate Device #1 K213184	Secondary Predicate Device K192295	Reference Device K162489	Remark
Electrical Safety	Complies 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	Comply with IEC 60601-1, IEC 60601-1-11, IEC60601-2-57	SAME
Photobiological Safety	Complies with IEC 62471 Complies with IEC 60601-2-57	Comply with IEC 62471	Comply with IEC 62471	IEC 62471	SAME
EMC	Complies with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	IEC 60601-1-2	SAME
Biocompatibility	Complies with ISO 10993-1, ISO 10993-5 and ISO 10993-10 ISO 10993-11 ISO 10993-23	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	SAME
Label and	Conforms to FDA	Conforms to FDA	Conforms to FDA	Conforms to FDA	SAME

Labeling	Regulatory Requirements	Regulatory Requirements	Regulatory Requirements	Regulatory Requirements	

Difference Analysis:
(Please explain any item that is not "SAME")

Note 1: The proposed device is battery powered, similar to the reference devices. The battery in the proposed device supports a longer battery life as well as fast charging. This does not affect the safety, effectiveness, or indications for use of the proposed device.

Note 2:

The target LED wavelength and variance range of the proposed, predicate, and reference device (variance ranges not provided) differ by just 3nm for Red Light at the high and low end of the output spectrum, with the proposed device being slightly higher. This represents a very minor difference and not one to affect equivalence. Furthermore, the proposed device has passed testing according to IEC60601-2-57. Therefore, there is no effect on safety, effectiveness, or intended use of the proposed device.

Note 3:

Predicate device and reference devices do not have vibration.

Proposed device is used for 7 less minutes per light treatment compared to the predicate device and is either identical or less than reference devices with respect to treatment time per light mode.

Substantially Equivalent (SE) Conclusion
Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicates K213184 and K192295 and Reference Device K162489.

(7) PERFORMANCE STANDARDS APPLIED:
A series of studies were completed to demonstrate the substantial equivalence of TheraFace Mask to the predicate/reference 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 Test （CSTBB2022120087）

ISO 10993-10 :2010, Biological evaluation of medical devices - part 10: Skin Sensitization Test (CSTBB2022120404R1)

ISO 10993-11:2017, Biological evaluation of medical devices - Part 11:

- Acute Systemic Toxicity Test （CSTBB2022110675R1）
- Material-mediated Pyrogens Test（CSTBB2022120016R1）

ISO 10993-23:2021, Biological evaluation of medical devices – Part 23: Tests for Intradermal Reactivity

（CSTBB2022110602R1

Electrical Safety and Electromagnetic Compatibility

IEC60601-1:2005 +CORR.1:2006+ CORR.2:2007+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (CHTSM22120256)

IEC 60601-1-2: 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic Compatibility. (CHTEM22120257)

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. (CHTSM22120260)

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. (CHTSM22120259)

IEC 62471:2006, Photobiological safety of lamps and lamp systems. (CHTSM22120258)

IEC 62133 Edition 2.0 2012-12, Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes - Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications (PNC221027191 01001)

(8) PERFORMANCE TESTING BENCH

Light power density test report (FP221125050384)

Usability Study Report DES-013.3

Device Temperature Range Testing Final Report Apr 16, 2023

Cleaning and Disinfection Testing

AAMI TIR30:2011/(R)2016 - A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices: Tests for Cleaning (CSTBB22100180)

AAMI TIR12:2010-Designing, testing and labeling reusable medical devices for reprocessing in health care facilities-Section 5: Tests for Disinfection (CSTBB22100180)

(9) PERFORMANCE TESTING CLINICAL

There were no clinical studies performed.

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