January 23, 2026

Shenzhen Rainbow Technology Co., Ltd.
% Youshan Gong
RA specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm.2401 Zhenye International Business Center
3101-90, Qianhai Rd.
Shenzhen, Guangdong 518052
China

Re: K253712
Trade/Device Name: LED Light Therapy Mask (RB-051, RB-061, RB-071, RB-052, RB-062, RB-072, RB-053, RB-063, RB-073)
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: November 22, 2025
Received: November 24, 2025

Dear Youshan Gong:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2026.01.23 14:05:53 -05'00'

Tanisha Hithe
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253712

Please provide the device trade name(s).

LED Light Therapy Mask (RB-051, RB-061, RB-071, RB-052, RB-062, RB-072, RB-053, RB-063, RB-073)

Please provide your Indications for Use below.

*Red+Infrared light: Treatment of full-face wrinkles.
*Red light: Treatment of full-face wrinkles.
*Infrared light: Provide topical heating for the purpose of elevating tissue temperature; arthritis and muscle spasm;relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.
*Blue light: Treatment of mild to moderate inflammatory acne.
*Red+Blue light: Treatment of mild to moderate inflammatory acne.
The device is intended to use LED light for the treatment of wrinkles and mild to moderate acne for adults in home healthcare environment.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510 (k) Summary

K253712

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information:

510(k) owner's name:	Shenzhen Rainbow Technology Co.,Ltd
Address:	3th Floor, No. 2, Dongwangyang Industry, Huangtian Community, Hangcheng Street, Bao'an District, Shenzhen City, Guangdong Province, China 518000
Contact person:	Layla Li
Position:	General Manager
Phone number:	+86 135 9032 9742
Email:	Layla@rainbowdo.com
Date of summary prepared:	2026-1-13

(2) Reason for the submission

New device, there were no prior submissions for the device.

(3) Proprietary name of the device

Trade name/model:	LED light therapy mask/Model: RB-051, RB-061, RB-071, RB-052, RB-062, RB-072, RB-053, RB-063, RB-073
Regulation name:	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Infrared, Therapeutic Heating(ILY)
Regulation number:	21 CFR 878.4810, 21 CFR 890.5500
Product code:	OHS, OLP, ILY
Review panel:	General & Plastic Surgery
Regulation class:	Class II

(4) Predicate devices

- **Predicate device**

Sponsor	Shenzhen Rainbow Technology Co., Ltd.
Device Name and Model	LED Light Therapy Mask (Model(s): RB-008, RB-030, RB-081, RB-008G, RB-008GB, RB-008J, RB-008JB)
510(k) Number	K243423

Product Code	OHS, OLP, ILY
Regulation Number	21 CFR 878.4810, 21 CFR 890.5500
Regulation Class	II

- **Reference device 1**

Sponsor	Shenzhen Kaiyan Medical Equipment Co., Ltd
Device Name and Model	Q-Rejuvalight Pro Facewear
510(k) Number	K230042
Product Code	OHS, OLP
Regulation Number	21 CFR 878.4810
Regulation Class	II

- **Reference device 2**

Sponsor	Dongguan Boyuan Intelligent Technology Co.,Ltd
Device Name and Model	LED Light Therapy Device(Models: KFB290, KFB291)
510(k) Number	K241857
Product Code	OHS, OLP, ILY
Regulation Number	21 CFR 878.4810, 21 CFR 890.5500
Regulation Class	II

- **Reference device 3**

Sponsor	Shenzhen SUNGPO HI-TECH Electronic Co., Ltd
Device Name and Model	LED Facial Mask
510(k) Number	K230351
Product Code	OHS, OLP
Regulation Number	21 CFR 878.4810
Regulation Class	II

- **Reference device 4**

Sponsor	Guangdong Newdermo Biotech Co.,Ltd
Device Name and Model	LED light therapy mask, Models: FM-01, FM-02, FM-03
510(k) Number	K242796
Product Code	OHS, OLP, ILY
Regulation Number	21 CFR 878.4810, 21 CFR 890.5500
Regulation Class	II

(5) Description/ Design of device:

LED Light Therapy Mask (Model: RB-051, RB-061, RB-071, RB-052, RB-062, RB-072,

RB-053, RB-063, RB-073) is a home use wearable LED phototherapy device which can help reduce wrinkles and acne and provide topical heating. LED Light Therapy Mask is consisting of main unit(mask), controller, Type-C charging cable and so on. There are 3 kinds of light, which include Red light (wavelength 630nm), Blue light (wavelength 465nm), Infrared light (wavelength 850nm).
All models can output 5 kinds of treatment modes: red+infrared, red, infrared, blue and red+blue light.

(6) Indications for use:

*Red+Infrared light: Treatment of full-face wrinkles.
*Red light: Treatment of full-face wrinkles.
*Infrared light: Provide topical heating for the purpose of elevating tissue temperature; arthritis and muscle spasm;relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.
*Blue light: Treatment of mild to moderate inflammatory acne.
*Red+Blue light: Treatment of mild to moderate inflammatory acne.

The device is intended to use LED light for the treatment of wrinkles and mild to moderate acne for adults in home healthcare environment.

(7) Materials

Component name	Material of Component	Body Contact Category	Contact Duration
LED Light Therapy Mask main unit and controller (RB-051, RB-061, RB-071, RB-052, RB-062, RB-072, RB-053, RB-063, RB-073)	ABS, Silicone	Surface-contacting device: Intact skin	>24 hours, ≤ 30 days
Straps (RB-051, RB-061, RB-071, RB-052, RB-062, RB-072, RB-053, RB-063, RB-073) (The main unit and straps are integrated)	Silicone	Surface-contacting device: Intact skin	>24 hours, ≤ 30 days

We have tested the device for biocompatibility by a reliable third-party lab. For details, please refer to "Biocompatibility Evaluation Report".

(8) Technological characteristics and substantial equivalence:

The LED Light Therapy Mask have the same intended use as the predicate device and reference devices. The technological characteristics such as wavelength, irradiance, power supply, are similar to the predicate device and reference devices. Any minor differences between the subject device and the listed predicate device and reference devices do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device and reference devices for its intended use.

Therefore, the LED Light Therapy Mask may be found substantially equivalent to its predicate devices and reference devices.

Item	Subject device	Predicate device K243423	Reference device 1 K230042	Reference device 2 K241857	Reference device 3 K230351	Reference device 4 K242796	Remark
510 (k) number	Pending	K243423	K230042	K241857	K230351	K242796	/
Trade name	LED light therapy mask	LED light therapy mask	Q-Rejuvalight Pro Facewear	LED Light Therapy Device(Models: KFB290, KFB291)	LED Facial Mask	LED light therapy mask, Models: FM-01, FM-02, FM-03	/
Manufacturer	Shenzhen Rainbow Technology Co.,Ltd	Shenzhen Rainbow Technology Co.,Ltd	Shenzhen Kaiyan Medical Equipment Co., Ltd	Dongguan Boyuan Intelligent Technology Co.,Ltd	Shenzhen SUNGPO HI-TECH Electronic Co., Ltd	Guangdong Newdermo Biotech Co.,Ltd	/
Regulation number	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810	21 CFR 878.4810 21 CFR 890.5500	Same
Regulation Name	Light Based Over The Counter Wrinkle Reduction	Light Based Over The Counter Wrinkle Reduction (OHS);	Light Based Over The Counter Wrinkle	Light Based Over The Counter Wrinkle Reduction(OHS),	Light Based Over The Counter Wrinkle	Light Based Over The Counter Wrinkle	Same

Item	Subject device	Predicate device K243423	Reference device 1 K230042	Reference device 2 K241857	Reference device 3 K230351	Reference device 4 K242796	Remark
	(OHS); Over-The-Counter Powered Light Based Laser For Acne(OLP); Infrared,Therapeutic Heating(ILY)	Over-The-Counter Powered Light Based Laser For Acne(OLP); Infrared,Therapeutic Heating(ILY)	Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP)	Over-The-Counter Powered Light Based Laser For Acne(OLP), Infrared Therapeutic Heating(ILY)	Reduction (OHS); Over-The-Counter Powered Light Based Laser For Acne(OLP);	Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Infrared Therapeutic Heating(ILY)	
Product code	OHS, OLP, ILY	OHS, OLP, ILY	OHS, OLP	OHS, OLP, ILY	OHS, OLP	OHS, OLP, ILY	Same
Class	Class II	Class II	Class II	Class II	Class II	Class II	Same
Indications for use/ Intended use	*Red+Infrared light: Treatment of full-face wrinkles. *Red light: Treatment of full-face wrinkles. *Infrared light: Provide topical heating for the purpose of elevating tissue temperature; arthritis and	• Red+Infrared light: Treatment of full-face wrinkles. • Red light: Treatment of full-face wrinkles. • Infrared light: Provide topical heating for the purpose of elevating tissue temperature;	The QRejuvalight Pro Facewear (Model: P19- 0023) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.	- Red light: Treatment of full-face wrinkles. - Infrared light: Provide topical heating for the purpose of elevating tissue temperature; arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase	LED Facial Mask is an over the counter device that is intended to use LED light for the treatment of wrinkles and mild to moderate acne.	Red light: Treatment of full-face wrinkles. Blue light: Treatment of mild to moderate inflammatory acne. Infrared light: Provide topical heating for the	Same

Item	Subject device	Predicate device K243423	Reference device 1 K230042	Reference device 2 K241857	Reference device 3 K230351	Reference device 4 K242796	Remark
	muscle spasm;relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. *Blue light: Treatment of mild to moderate inflammatory acne. *Red+Blue light: Treatment of mild to moderate inflammatory acne. The device is intended to use LED light for the treatment of wrinkles and mild	arthritis and muscle spasm;relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. • Blue light: Treatment of mild to moderate inflammatory acne. • Red+Blue light: Treatment of mild to moderate inflammatory acne. The device is intended to use LED light for the treatment of wrinkles and mild to		local blood circulation. - Red+Infrared Light: Treatment of full-face wrinkles. - Amber light: Treatment of full-face wrinkles. - Blue light: Treatment of mild to moderate inflammatory acne. - Mixed light(Red+Blue +Infrared): Treatment of mild to moderate inflammatory acne.		purpose of elevating tissue temperature; arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. Mixed light:Treatment of mild to moderate inflammatory acne.	

Item	Subject device	Predicate device K243423	Reference device 1 K230042	Reference device 2 K241857	Reference device 3 K230351	Reference device 4 K242796	Remark
	to moderate acne for adults in home healthcare environment.	moderate acne for adults in home healthcare environment.					
Location for use	Face	Face	Face	Face	Face	Face	Same
OTC or prescription	OTC	OTC	OTC	OTC	OTC	OTC	Same
Power supply	Output: 5V 1A Rechargeable Lithium battery	Output: 5V 1A Rechargeable Lithium battery	Input: 5V, 50/60Hz, 2A Li-ion Polymer Battery: 3.7V, 600mAh, 2.22Wh	Input: 100 -240 V, 50 / 60 Hz Output: 5V, 1A Lithium ion battery: 1300mAh	An external adapter Input: AC 100-240V 50-60Hz 0.2A Output: DC 12V 0.5A	Input: 100-240V, 50/60Hz, 0.25 A Output: DC 5 V, 500 mA	Same
Light source		Light Emitting Diodes		Light Emitting Diodes	Light Emitting Diodes	Light Emitting Diodes	Same
Wavelength	Red: 620nm Blue: 465nm Infrared: 850nm	Red: 620nm Blue: 460nm Infrared: 850nm	630nm, 880nm, 415nm 605nm, 660nm,	635nm ± 5nm visible red light; 850nm ± 5nm Invisible red light; 465±5nm blue light; 605 ± 5nm amber	Blue: 465nm±5nm Red: 625nm±5nm Amber: 605nm±5nm	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm	Similar **Note 1**

Item	Subject device	Predicate device K243423	Reference device 1 K230042	Reference device 2 K241857	Reference device 3 K230351	Reference device 4 K242796	Remark
				light			
Irradiance	1) Red light: 20mw/cm²-10%/+30%, that is 18~26mw/cm² 2) Infrared light: 4mW/cm²-10%/+30%, that is 3.6~5.2mw/cm² 3) Blue light: 35mw/cm²-10%/+30%, that is 31.5~45.5mw/cm² 4) Red + Infrared light: 35mw/cm²-10%/+30%, that is	Red+IR: 45.5mW/cm² Red light: 53.2mW/cm² Infrared light: 4mW/cm² Blue light: 58.7mW/cm² Red+Blue light: 33.6mW/cm²	605nm: 15±5mW/cm² 630nm: 20±5mW/cm² 660nm: 25±5mW/cm² 880nm: 10±5mW/cm² 415nm: 25±5mW/cm² Total: 70mW/cm²(wrinkle)-(605nm+630nm+660nm+880nm) 45mW/cm²(acne)-(630nm+415nm)	Red: 25mW/cm²; IR: 3mW/cm²; Red+IR: 30mW/cm²; Blue: 18mW/cm²; Amber: 20mW/cm²; Mixed light: 9mW/cm²;	Blue: 15~63mW/cm² Red: 31~75mW/cm²	Red light: 2.0~3.0mW/cm² Blue light: 2.0~4.0mW/cm² Infrared light: 2.0~4.0 mW/cm² Mixed light: 9.0~12.0 mW/cm²	Different **Note 2**

Item	Subject device	Predicate device K243423	Reference device 1 K230042	Reference device 2 K241857	Reference device 3 K230351	Reference device 4 K242796	Remark
	31.5~45.5mw/cm² 5) Red + Blue light: 40mw/cm²-10%/+30%, that is 36~52mw/cm²						
Treatment time	10-minute at a time. 3-4 treatment a week, reduce to 1-2 treatment a week once the results shown.	5-minute or 10-minute at a time. 3-4 treatment a week, reduce to 1-2 treatment a week once the results shown.	3 minutes per treatment	For red, blue and red+infrared: 10, 20, 30 minutes For infrared, amber light and mixed light: 10, 20 minutes.	10 minutes/day, 3 times per week	**Manual Mode:** 15 minutes each time, **Automatic Mode:** 10 minutes each time.	Same
Dimensions (mm)	LED Mask: About 63.4 X 22.8 X 15.4 (cm) Remote control: About 4.5 X 13.3 X 3.2 (cm)	Model RB-030,RB-081,RB-008: About 19.5 X 22.3 X 9.3 (cm) Model RB-008G,RB-008GB: About 27.5 X 20.5 X	No publicly available	**KFB290:** Approximately 302 mm x 197 mm x 22 mm **KFB291:** Approximately 412 mm x 195 mm x 22 mm	Not publicly available	**FM-01:** 207 * 277 * 43 mm, **FM-02:** 198 * 383 * 33.5 mm, **FM-03:** 237.5 * 108 * 8.1 mm	Different **Note 3**

Item	Subject device	Predicate device K243423	Reference device 1 K230042	Reference device 2 K241857	Reference device 3 K230351	Reference device 4 K242796	Remark
		0.3 (cm) Model RB-008J,RB-008JB: About 27.8 X 20.8 X 0.38 (cm)					
Weight	LED Mask: About 338 g Remote control: About 50 g	Model RB-030, RB-081, RB-008: About 391 g Model RB-008G, RB-008GB: About 120 g Model RB-008J,RB-008JB: About 391 g	No publicly available	Not publicly available	Not publicly available	Not publicly available	Different **Note 3**
Compliance with voluntary standards	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-83; IEC 62471	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-83; IEC 62471	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-57; IEC 62471; IEC 62133-2	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-83; IEC 62471	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-57 IEC62471	IEC 60601-1; IEC 60601-1-2	Same
Biocompatibility feature	All body-contacting materials are complied with	All body-contacting materials are complied with ISO10993-5, ISO 10993-10, ISO	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	Comply with ISO10993-1, ISO10993-5 and ISO10993-10	All body-contacting materials are complied with	Same

Item	Subject device	Predicate device K243423	Reference device 1 K230042	Reference device 2 K241857	Reference device 3 K230351	Reference device 4 K242796	Remark
	ISO10993-5, ISO 10993-10, ISO 10993-23	10993-23				ISO10993-5 and ISO 10993-10	

Comparison in details:

Note 1:

Though the wavelength of subject device is a little different from the predicate device, the wavelength of the subject device can be basically covered by the predicate devices and reference devices' range and they all comply with IEC 60601-2-83 and IEC 62471 requirements, so this difference will not raise any safety or effectiveness issue.

Note 2:

Though the irradiance of subject device is a little different from the predicate device and reference devices, the irradiance of subject device is within the range of the minimum and maximum value of the predicate device and reference devices, and the subject device complies with IEC 60601-2-83 and IEC 62471 requirements, so this difference will not raise any safety or effectiveness issue.

Note 3:

Though the dimension and weight are different from the predicate device and reference devices, this difference is insignificant and do not raise any safety or effectiveness problems.

Conclusions

LED Light Therapy Mask are substantially equivalent to the predicate device and reference devices.

(9) Non-clinical studies and tests performed:

Non-clinical testings have been conducted to verify that the LED Light Therapy Mask meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the subject device complies with the following standards:

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, 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 Edition 2.1 2020-07 CONSOLIDATED VERSION, 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 60601-2-83:2019/AMD1:2022, Medical Electrical Equipment - Part 2-83: Particular requirements for the basic safety and essential performance
- IEC 62471 First edition 2006-07, Photobiological safety of lamps and lamp systems
- IEC 62133-2 Edition1.0 2017-02, 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 - Part 2: Lithium systems

The device has been tested for biocompatibility, it complies with the following standards.

- ISO 10993-5 Third edition 2009-06-01, Biological Evaluation of Medical Devices - Part 5: Tests for InVitro Cytotoxicity
- ISO 10993-10 Fourth edition 2021-11, Biological Evaluation of Medical Devices - Part 10: Tests for Skin Sensitization
- ISO 10993-23 First edition 2021-01 Biological Evaluation of Medical Devices - Part 23: Tests for Irritation

We have also conducted:

- Software verification and validation test according to the requirements of the FDA "Content of Premarket Submissions for Device Software Functions"

(10) Conclusion

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device LED Light Therapy Mask is as safe, as effective, and performs as well as the legally marketed predicate device.