February 23, 2023

Guangdong Newdermo Biotech Co.,Ltd
Annie Cai
Certificate Engineer
Building C28. Huachuang Industrial Park, Jinshan Avenue
Shiji Town, Panyu
Guangzhou, 511450
China

Re: K223544
Trade/Device Name: LED light therapy mask (FM-01, FM-02, FM-03)
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 24, 2022
Received: November 25, 2022

Dear Annie Cai:

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.

510(k) Number *(if known)*
K223544

Device Name
LED light therapy mask (FM-01, FM-02, FM-03)

Indications for Use *(Describe)*
Red light: Treatment of full-face wrinkles.
Blue light: Treatment of mild to moderate inflammatory acne.
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.
Mixed light: Treatment of mild to moderate inflammatory acne.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary
K223544

510（K） Summary

Prepared in accordance with the content and format regulatory requirements of 21 CFR Part 807.92

1. Submitter:

510(k) owner's name:	Guangdong Newdermo Biotech Co.,Ltd
Address:	Building C28. Huachuang Industrial Park, Jinshan Avenue, Shiji Town, Panyu, Guangzhou, 511450 P.R. China
Tel:	+86(020) 31105688
Contact person:	Annie Cai
Email：	caidejiao@qq.com
Preparing date:	February 22, 2023

2. Device name and classification:

Device Name:	LED light therapy mask
Model:	FM-01, FM-02, FM-03
Classification Name/ Product code:	21 CFR 878.4810 OHS 21 CFR 878.4810 OLP 21 CFR 890.5500 ILY
Regulatory Class:	Class II

3.Premarket Notification Class III Certification and Summary

Not applicable, the subject device is Class II.

4. Predicate Device(s):

1) Predicate device1

Sponsor:	NINGBO HESI ELECTRIC CO., LTD
Device name:	LED FACIAL LIGHT THERAPY MASK, FLEXIBLE LED LIGHT THERAPY
510(k) Number:	K200983
Product Code:	OHS, OLP, ILY

2) Predicate device2

Sponsor:	Hunan Guangye Biotechnology Co., Ltd.
Device name:	Beauty LED Mask

510(k) Number: K221151

Product Code: OHS, OLP

3）Predicate device3

Sponsor: Zhongshan Bisen Plastic Electronic Products Co.,Ltd.

Device name: RED Light Device

510(k) Number: K162489

Product Code: OHS

4）Predicate device4

Sponsor: Theragun, Inc.

Device name: TheraFace LED

510(k) Number: K212155

Product Code: OHS, OLP

5) Reference device

Sponsor: Xuzhou Kernel Medical Equipment Co., Ltd.

Device name: LED Light Therapy Device, KN-7000L

510(k) Number: K222751

Product Code: GEX

5. Reason for Submission

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

6. Pre-Submission, IDE

Not applicable, there is no prior submission.

7. Device Description:

LED light therapy mask is a home use wearable LED phototherapy device which can help solve various skin problems. LED light therapy mask is consisting of mask, controller, adapter, USB cable and straps.

There are 4 kinds of light which include Red light (wavelength 620nm), Blue light (wavelength 460nm), Infrared light (wavelength 850nm), Mixed light (wavelength 620nm and 850nm and 460nm).

8. Intended Use:

Red light: Treatment of full-face wrinkles.

Blue light: Treatment of mild to moderate inflammatory acne.

Infrared light: Provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, 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.

9. Predicate Device Comparison

Item	Subject Device	Predicate device1(K200983)	Predicate Device2(K221151)	Comparison Result
Trade name	LED light therapy mask	LED FACIAL LIGHT THERAPY MASK, FLEXIBLE LED LIGHT THERAPY	Beauty LED Mask	/
510 (k) number	K223544	K200983	K221151	/
Manufacturer	Guangdong Newdermo Biotech Co.,Ltd	NINGBO HESI ELECTRIC CO., LTD	Hunan Guangye Biotechnology Co., Ltd.	/
Regulation number	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810, 21 CFR 890.5500	21 CFR 878.4810	Same
Regulation Name	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Infrared, Therapeutic Heating(ILY)	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Lamp, Infrared, Therapeutic Heating(ILY)	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP)	Same
Product code	OHS, OLP, ILY	OHS, OLP, ILY	OHS, OLP	Same
Classification	II	II	II	Same
Indications for use/ Intended use	Red light: Treatment of full-face wrinkles. Blue light: Treatment of mild to moderate inflammatory acne.	The LED FACIAL LIGHT THERAPY MASK (Model: HK207) is intended to: - The device	The device is intended to use LED light for the treatment of wrinkles and mild to moderate acne.	Similar Note2

	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. Mixed light: Treatment of mild to moderate inflammatory acne.	emitting energy in the blue is intended to reduce the mild to moderate inflammatory acne vulgaris. - The device emitting energy in the red and infrared spectrum is intended for the treatment of full-face wrinkles. The FLEXIBLE LED LIGHT THERAPY (Model: HK209) is intended to: - The device emitting energy in the blue is intended to reduce the mild to moderate inflammatory acne vulgaris. - The device emitting energy in the red and infrared spectrum is intended for the treatment of full-face wrinkles. - The device is intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for		

		the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.		
Location for use	Face and body	Entire Face and body	Face	Same
OTC or prescription	OTC	OTC	OTC	Same
Power supply	Input: 100-240 V~, 50/60 Hz, 0,25 A Output: DC 5 V, 500 mA	Input: 100 – 240Vac, 2.0 A, 50/60Hz	Input: 100 -240 V ~ 50 /60 Hz Output: 5V 1A	Similar Note4
Light source	LED	LED	LED	same
Wavelength	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm	465nm, 640nm, 880nm	Red (637nm±5nm) and IR (854nm±5nm); Blue (465±5nm)	Compare with predicate device 4 Similar Note 5
LED Intensity	Red light: 2.0~3.0 mW/cm^2 Blue light:2.0~4.0 mW/cm^2 Infrared light: 2.0~4.0 mW/cm^2 Mixed light: 9.0~12.0 mW/cm^2	6.5 mW/cm^2	Red+IR: 25.5mW/cm^2 Blue: 1.36mW/cm^2	Similar Note6
Treatment time	Manual Mode: 15minutes each time, Automatic Mode: 10minutes each time. 3-4 treatment a week, reduce to 1-2	3 times a week for 30 min. 4 weeks	10min each time	Compare with predicate device 3 Similar Note7

	treatment a week once the results shown.			
Dimensions (mm)	FM-01: 207X277X43mm, FM-02: 198X383X33.5mm, FM-03: 237.5X108X8.1mm	Not public	LED Mask: Approximately 183 mm x 238 mm x 98 mm Controller: 100mm x 50 mm x 21.5 mm	/
Electrical safety	IEC 60601-1; IEC 60601-1-2	IEC 60601-1; IEC 60601-1-2	IEC 60601-1; IEC 60601-1-2	Same
Biocompatibility feature	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	Same

Item	Subject Device	Predicate device3(K162489)	Predicate Device4(K212155)	Comparison Result
Trade name	LED light therapy mask	RED Light Device	TheraFace LED	/
510 (k) number	K223544	K162489	K212155	/
Manufacturer	Guangdong Newdermo Biotech Co.,Ltd	Zhongshan Bisen Plastic Electronic Products Co.,Ltd.	Theragun, Inc.	/
Regulation number	21 CFR 878.4810, 21 CFR 890.5500	21 CFR 878.4810	21 CFR 878.4810	Similar Note1
Regulation Name	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Infrared, Therapeutic Heating(ILY)	Light Based Over The Counter Wrinkle Reduction(OHS),	Light Based Over The Counter Wrinkle Reduction(OHS),	Similar Note1
Product code	OHS, OLP, ILY	OHS	OHS, OLP	Similar Note1
Classification	II	II	II	Same

Indications for use/ Intended use	Red light: Treatment of full-face wrinkles Blue light: Treatment of mild to moderate inflammatory acne. 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. Mixed light: Treatment of 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.	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.	Similar Note2
Location for use	Face and body	/	Face	Similar Note3
OTC or prescription	OTC	OTC	OTC	Same
Power supply	Input: 100-240 V~, 50/60 Hz, 0,25 A Output: DC 5 V, 500 mA	Adaptor:100~240V AC 50/60Hz Lithium battery: 2x3.7V	Lithium battery :2x3.7V	Similar Note4
Light source	LED	LED	LED	Same
Wavelength	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm	Red: 633 ±5nm Infrared: 830 ±5nm	Red light: 633nm±10nm Blue light: 415nm±10nm Red+IR: 633±10nm / 830nm±10nm	Compare with predicate device 4 Similar Note 5
LED Intensity	Red light: 2.0~3.0 mW/cm^2	125 mW/cm^2 70 mW/cm^2 (633	Red light 73±5 mW/cm^2	Compare with

	Blue light:2.0~4.0 mW/cm^2 Infrared light: 2.0~4.0 mW/cm^2 Mixed light: 9.0~12.0 mW/cm^2	nm); 55 mW/cm^2 (830nm)	Blue light 64±5 mW/cm^2 Red+IR: 73±5/55±5 mW/cm^2	predicate device 3 Similar Note6
Treatment time	Manual Mode: 15minutes each time, Automatic Mode: 10minutes each time. 3-4 treatment a week, reduce to 1-2 treatment a week once the results shown.	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).	Red light: 5 - 7 minutes per treatment zone Blue: 5 - 7 minutes per treatment zone Red+IR: 5 - 7 minutes per treatment zone	Compare with predicate device 3 Similar Note7
Dimensions (mm)	FM-01: 207X277X43mm, FM-02: 198X383X33.5mm, FM-03: 237.5X108X8.1mm	/	/	/
Electrical safety	IEC 60601-1; IEC 60601-1-2	IEC 60601-1; IEC 60601-1-2	IEC 60601-1; IEC 60601-1-2	Same
Biocompatibility feature	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	Same

Comparison in Detail(s):

Note1

The Regulation number, Regulation Name, Product code of predicate1 are not identical to the subject device, all these device are process similar intended use and use very similar light wavelengths to get the intended purpose. This slight deference will not raise safety and effective issue.

Note2

The Indications for use/ Intended use of Red light, Blue light , Infrared light of the subject device is the same as that of primary device K200983. The Indications for use/ Intended use of mixed light of the subject device is the same as that of secondary device K221151.

Note3

The treatment location of the subject device is the same as the predicate device K200983 but identical the other predicate device. The difference in applicable location will not raise safety and effective issue.

Note4

The power supply of devices are very similar but not identical, the IEC60601-1test demonstrated the safety of the power adapter. The slight difference will not raise safety and effective issue.

Note5

The light wavelength is very similar but not identical. The subject device emits blue light, red light and IR light. In the mixed light mode, the subject device emits blue light, red light, IR light simultaneously, while the reference device K222751 can emit red, blue, IR light simultaneously and it has been demonstrated that emit three lights simultaneously is safe and effect. Besides, the subject device has passed IEC60601-2-57 test, the slight difference will not raise safety and effective issue.

Note6

The LED Intensity of these devices are different, and the LED intensity of the subject device is low and subject device has passed IEC60601-2-57 test, the slight difference will not raise safety and effective issue.

Note7

The treatment time of these devices are very similar but not identical, treatment is one of the factors to get the intended purpose. What's more, the subject device has IEC60601-1, IEC60601-2-57 test, the slight difference will not raise safety and effective issue.

All the differences don't affect the safety and effectiveness which is concluded after all the required testing, so no safety and effectiveness issues relating to the product come into conclusion.

10. Performance Data:

Non-clinical data:

Non-clinical tests have been conducted to verify that the Beauty LED 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:

- ANSI AAMI ES 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

Biocompatibility Test

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

- 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.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Clinical data: Not applicable.

Summary

Based on the non-clinical and clinical performance as documented in the system development, the subject devices were found to have a safety and effectiveness profile that is similar to the predicate device.

11. Conclusion

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that LED light therapy mask should perform as intended in the specified use conditions, and all the data demonstrate that the subject devices perform comparably to the predicate device that is currently marketed for the same intended use. In other words, the subject device (LED light therapy mask) is Substantial Equivalent to the predicate devices K200983, K221151, K162489 and K212155.