March 16, 2026

Shenzhen Desida Technology Co., Ltd.
% Bing Huang
Registration Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm.2401 Zhenye International Business Center, # 3101-90,
Qianhai Rd.
Shenzhen, Guangdong 518052
China

Re: K254079
Trade/Device Name: LED Light Therapy Mask (Models: T2, RLD10)
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: December 18, 2025
Received: December 18, 2025

Dear Bing Huang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.03.16 18:27:15 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254079

Device Name
LED light therapy mask (Models: T2, RLD10)

Indications for Use *(Describe)*
* Red+Infrared 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.

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

K254079

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 Desida Technology Co., Ltd.
Address:	5th Floor, Building A, Sanmin Industrial Zone, Shilongzai, Shuitian Community, Shiyan Street, Baoan District, Shenzhen Guangdong, CN 518109
Contact person:	Yong Gong
Position:	General Manager
Phone number:	+86-13689585641
Email:	40888122@qq.com
Date of summary prepared:	2026-3-16

(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 (Models: T2, RLD10)
Regulation name:	Light Based Over The Counter Wrinkle Reduction (OHS), Over-The-Counter Powered Light Based Laser For Acne (OLP)
Regulation number:	21 CFR 878.4810
Product code:	OHS, OLP
Review panel:	General & Plastic Surgery
Regulation class:	Class II

(4) Predicate devices

- **Primary Predicate device 1**

Sponsor	Dongguan Boyuan Intelligent Technology Co., Ltd.
Device Name and Model	LED Light Therapy Device (KFB290, KFB291, KB265, KB293)
510(k) Number	K241857
Product Code	OHS, OLP, ILY
Regulation Number	21 CFR 878.4810
Regulation Class	II

- **Reference device 2**

Sponsor	Shenzhen SUNGPO HI-TECH Electronic Co.,Ltd
Device Name and Model	LED Facial Mask (Models: MZ-01, NEWKEY-01, SP-FM-01)
510(k) Number	K230351
Product Code	OHS, OLP
Regulation Number	21 CFR 878.4810
Regulation Class	II

- **Reference device 3**

Sponsor	Shenzhen Nuon Medical Equipment Co., Ltd
Device Name and Model	Radiant Renewal Skincare Wand (Models: HD-44, HD-44A, HD-44B, HD-44C, HD-69, HD-69A, HD-69B)
510(k) Number	K242151
Product Code	OHS, OLP
Regulation Number	21 CFR 878.4810
Regulation Class	II

- **Reference device 4**

Sponsor	Shenzhen Sungrow LED Technology Co., Ltd.
Device Name and Model	LED Light Therapy Mask (G15, G15P, G15K, G11P, G11, G10, G13, G14, G17, VISO, PRANA, Chin2Chest, BBLFACEMASK)
510(k) Number	K250830
Product Code	OHS, OLP
Regulation Number	21 CFR 878.4810
Regulation Class	II

- **Reference device 5**

Sponsor	SharkNinja Operating, LLC
Device Name and Model	CryoGlow (FW3XXXX)
510(k) Number	K242796
Product Code	OHS, OLP
Regulation Number	21 CFR 878.4810
Regulation Class	II

(5) Description/ Design of device:

LED Light Therapy Mask (Models: T2, RLD10) is a home use wearable LED phototherapy

device which can help reduce wrinkles and acne. LED Light Therapy Mask consists of main unit (mask, safety goggles), controller, Type-C charging cable and straps. There are 3 kinds of light, which include Red light (wavelength 630nm), Blue light (wavelength 470nm), Infrared light (wavelength 850nm).
All models can output 3 kinds of treatment modes: red+infrared, blue and red+infrared+blue light.

(6) Indications for use:

* Red+Infrared 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.

(7) Materials

Component name	Material of Component	Body Contact Category	Contact Duration
Enclosure of controller	ABS	Surface-contacting device: Intact skin	>24 hours, ≤ 30 days
Mask and straps	Silicone and colour toner	Surface-contacting device: Intact skin	>24 hours, ≤ 30 days

(8) Technological characteristics and substantial equivalence:

The LED Light Therapy Mask is intended to use LED light for the treatment of wrinkles and mild to moderate inflammatory acne.

Based on FDA Medical Device Database, we can find its similar devices. And we adopt K241857 as its primary predicate device and K230351, K242151, K250830 and K242796 as its reference devices. Through the comparisons, we come to a conclusion that these devices have the same intended use, similar technological characteristics and principles of operation.

The details are as follows:

Item	Subject device	Primary Predicate device 1 K241857	Reference device 2 K230351	Reference device 3 K242151	Reference device 4 K250830	Reference device 5 K242796	Remark
Trade name	LED Light Therapy Mask/ Models: T2, RLD10	LED Light Therapy Device (Model(s): KFB290, KFB291, KFB265, KFB293)	LED Facial Mask (Models: MZ-01, NEWKEY-01, SP-FM-01	Radiant Renewal Skincare Wand (Models: HD-44, HD-44A, HD-44B, HD-44C, HD-69, HD-69A, HD-69B)	LED Light Therapy Mask, (G15, G15P, G15K, G11P, G11, G10, G13, G14, G17, VISO, PRANA, Chin2Chest, BBLFACEMASK)	CryoGlow (FW3XXXX)	/
510 (k) number	Pending	K241857	K230351	K242151	K250830	K242796	/
Manufacturer	Shenzhen Desida Technology Co., Ltd.	Dongguan Boyuan Intelligent Technology Co., Ltd.	Shenzhen SUNGPO HI-TECH Electronic Co.,Ltd	Shenzhen Nuon Medical Equipment Co., Ltd	Shenzhen Sungrow LED Technology Co.,Ltd.	SharkNinja Operating, LLC	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810, 21 CFR 890.5500	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	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)	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Infrared, Therapeutic Heating(ILY)	Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP)	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP)	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP)	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP)	Same
Product code	OHS, OLP	OHS, OLP, ILY	OHS, OLP	OHS, OLP	OHS, OLP	OHS, OLP	Same
Class	II	II	II	II	II	II	Same
Indications for use/ Intended use	* Red+Infrared 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.	KFB290, KFB291: a. Red light: Treatment of full-face wrinkles. b. Infrared light: Provide topical heating for the purpose of elevating tissue temperature; arthritis and muscle spasm; relieving stiffness; promoting the	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.	The Radiant Renewal Skincare Wand (Models:HD-44,HD-44A, HD-44B,HD-69,HD-69A) is an over-the-counter device intended for the treatment of full-face wrinkles. The Radiant Renewal Skincare Wand	Red light: Treatment of full-face wrinkles. Yellow light: Treatment of full-face wrinkles. Red+Infrared light: Treatment of full-face wrinkles. Blue light: Treatment of mild to moderate inflammatory acne.	The CryoGlow LED mask emits energy in the red and infrared light spectrum for the treatment of fine lines and wrinkles and in the red, blue, and infrared light spectrum for the treatment of mild-to-moderate inflammatory acne.	Similar **Note 1**

Item	Subject device	Primary Predicate device 1 K241857	Reference device 2 K230351	Reference device 3 K242151	Reference device 4 K250830	Reference device 5 K242796	Remark
		relaxation of muscle tissue; and to temporarily increase local blood circulation. c. Red+Infrared Light: Treatment of full-face wrinkles. d. Amber light: Treatment of full-face wrinkles. e. Blue light: Treatment of mild to moderate inflammatory acne. f. Mixed light(Red+Blue +Infrared): Treatment of mild to moderate inflammatory acne.		(Models:HD-44C,HD-69B) is an over-the-counter device intended for the treatment of mild to moderate inflammatory acne.	Mixed light (Red+Blue+Infrared): Treatment of mild to moderate inflammatory acne.		
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	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	Lithium battery: For models HD-44,HD-44A, HD-44B,HD-44C: 3.7V,30mAh; For models HD-69,HD-69A, HD-69B: 3.7V,130mAh	Input: AC 100-240V 50-60Hz 0.2A Output: DC 5V/2A DC 3.7V 5000 mAh Liion Battery	2 Li-Ion Batteries 3.6V, 2350 mAh total, charged by USB-A to USB-C charging cord to USB-A charging block	Different **Note 2**
Light source	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Same
Wavelength	630nm ±10nm visible red light; 850nm±10nm non-visible red light; 470±10nm blue light;	635nm ± 5nm visible red light; 850nm±5nm Invisible red light; 465±5nm blue light; 605±5nm amber light	625nm±5nm, 465nm±5nm, 605±5nm	HD-44:Red+IR 630±10nm&830±10nm HD-44A/HD-69A:Red 630±10nm; HD-44B/HD-69:Yellow 590±10nm; HD-44C/HD-69B:Blue 415±10nm;	Blue: 415 nm+/-10nm Red: 660 nm+/-10nm Yellow: 590 nm+/- 10nm Near-Infrared: 850nm+/-10nm	630 ±10nm, 830 ± 10nm, 415 ±10nm	Same

Item	Subject device	Primary Predicate device 1 K241857	Reference device 2 K230351	Reference device 3 K242151	Reference device 4 K250830	Reference device 5 K242796	Remark
LED power	Red+Infrared light Mode Level 1: 30~45mW/cm^2, Level 2: 45~60mW/cm^2, Level 3: 60~70mW/cm^2 Blue light Mode Level 1: 40~50mW/cm^2, Level 2: 50~60mW/cm^2, Level 3: 60~65mW/cm^2 Mixed light Mode Level 1: 40~50mW/cm^2, Level 2: 50~60mW/cm^2, Level 3: 60~65mW/cm^2	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	HD-44:Red+IR 630±10nm:20~50 830±10nm:25~55 Total:45~105 HD-44A&HD-69A:Red 630±10nm:30~50 HD-44B/HD-69:Yellow 590±10nm:10~30 HD-44C/HD-69B:Blue 415±10nm:35~50	Mode 1: Red:15-22mW/cm^2 Mode 2: Yellow: 20-30mW/cm^2 Mode 3: Red-near infrared: 20-30mW/cm^2 Mode 4: Blue-red-near infrared: 25-45mW/cm^2 Mode 5: Blue: 13-23mW/cm^2 Mode 6: Yellow: 20-30mW/cm^2, red-near infrared: 20-30mW/cm^2, blue: 13-23mW/cm^2	**Skin Sustain:** Blue 59.8 ± 7 mW/cm², Red 17.0 ± 5mW/cm², IR 51.2 ± 5 mW/cm² Total mode = 128 mW/cm² **Skin Clearing [Step 1]:** Blue 64 ± 8 mW/cm², IR 64.0 ± 5 mW/cm² Total mode =128 mW/cm² **Skin Clearing [Step 2]:** Blue 55 ± 6 mW/cm², Red 73 mW/cm² Total mode =128 mW/cm² **Skin Clearing [Step 3]:** Red 73 mW/cm², IR 55 ± 5mW/cm², Total mode =128 mW/cm² **Better Aging:** Red 64 ± 5mW/cm², IR 64 ± 5 mW/cm² Total mode = 128 mW/cm²	Similar **Note 3**
Treatment time	10, 20, 30minutes	For red, blue and red+infrared: 10, 20, 30 minutes	10 minutes/day, 3 times per week	5 minutes per treatment	No publicly available	Skin Sustain: 4.3 min (daily after 8 weeks) Skin Clearing: 8.4 min (daily for at least 8 weeks) Better Aging: 6.4 min(daily for at least 8 weeks) Under-eye cooling: may be used with LED treatments or can be used without LEDs active. Variable	Same

Item	Subject device	Primary Predicate device 1 K241857	Reference device 2 K230351	Reference device 3 K242151	Reference device 4 K250830	Reference device 5 K242796	Remark
						cooling settings are available and may be adjusted by the user. Cooling is intended for refreshing/invigorating/soothing the skin only.	
Dimensions (mm)	LED Mask: 306mm*198mm*6mm Controller: 110*32*27mm	KFB290: Approximately 302 mm x 197 mm x 22 mm KFB291: Approximately 412 mm x 195 mm x 22 mm	No publicly available	No publicly available	Mask body: 310*207*4.5mm Controller: 130*41*21mm	No publicly available	Different **Note 4**
Compliance with voluntary standards	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-83; IEC 62471; IEC 62133-2	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-83; IEC 62471; IEC 62133-2	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-57; IEC 62471	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-57; 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 60601-2-83; IEC 62471;	Same

Comparison in details:

Note 1:
Though the indication for use of subject device is little different from the primary predicate devices, the specific description of indication for use can find in primary predicate device. So this difference should not raise any safety/effectiveness questions.

Note 2:
The power supply for the subject device is different from that of the predicate device, however the lithium battery of the subject device has passed IEC 62133-2 test and the power adapter has been assessed for electrical safety along with the main unit, so this difference should not raise any safety/effectiveness questions.

Note 3:
Although there is slight difference of “LED Power” between subject device and predicated devices, both the subject device and predicate device have the same treatment wavelengths (630nm, 850nm, 470nm) and total power density designed in treating the wrinkles and the acne. So the slight difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Note 4:
Although the appearance, dimensions are different between the subject and predicate device, these differences are insignificant and do not raise any safety/effectiveness problems.

Conclusion:
LED Light Therapy Mask is 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 60601-2-83:2022, Medical Electrical Equipment - Part 2-83: Particular requirements for the basic safety and essential performance
- IEC 62471, Photobiological safety of lamps and lamp systems
- IEC 62133-2 Edition 5.0 2021-09, 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

We have also conducted:

- Software verification and validation test according to the requirements of the FDA Guidance Document "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.