August 4, 2026

Duplex International Trading Limited
JunYi Xing
Certificate Engineer
B1, 10/F, Block 2, Golden Dragon Ind Center, 162-170 Tai Lin Pai Rd., Kwai Chung, N.T., Hong Kong
Hongkong,
China

Re: K261496
Trade/Device Name: LED Light Therapy Masks (PE748, PE749, PE756)
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 6, 2026
Received: May 6, 2026

Dear JunYi Xing:

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: 2026.08.04 16:09:40 -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)*
K261496

Device Name
LED Light Therapy Masks (PE748, PE749, PE756)

Indications for Use *(Describe)*
The LED Light Therapy Mask (Model: PE748) is an Over-the-Counter (OTC) device,
the Red light mode (Red + Near-Infrared light) intended for treatment of wrinkles;
The Purple Light (Red + Blue light) mode intended for mild to moderate inflammatory acne.

The LED Light Therapy Mask (Model: PE749) is an Over-the-Counter (OTC) device,
For the face mask:
The Red light mode (Red + Near-Infrared light) intended for treatment of wrinkles;
The Purple Light (Red + Blue light) mode intended for mild to moderate inflammatory acne.
For the neck mask:
The Red light mode (Red + Near-Infrared light) intended for treatment of wrinkles;

The LED Light Therapy Mask (Model: PE756) is an Over-the-Counter (OTC) device,
The Red light mode (Red + Near-Infrared light) intended for treatment of 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.

510（K）Summary - K261496

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

1. Submitter:

510(k) owner's name:	Duplex International Trading Limited
Establishment Registration Number:	3013178978
Address:	B1, 10/F, Block 2, Golden Dragon Ind Center, 162-170 Tai Lin Pai Road, Kwai Chung, N.T., Hong Kong
Tel:	+86(020) 31105688
Contact person (including title):	Junyi Xing (Manager)
Email：	sales13@newdermo.com
Preparing date:	April 30, 2026

2. Device name and classification:

Device Name:	LED Light Therapy Mask
Model:	PE748; PE749; PE756
Classification Name	Light Based Over The Counter Wrinkle Reduction Over-The-Counter Powered Light Based Laser For Acne
Product code:	OHS, OLP
Regulation Number	21 CFR 878.4810
Regulatory Class:	Class II
Review Panel:	General & Plastic Surgery

3.Premarket Notification Class III Certification and Summary

Not applicable, the subject device is Class II.

4. Predicate Device(s):

1) Predicate device1

Sponsor:	Light Tree Ventures Europe B.V.
Device name:	Q-Rejuvalight Pro Facewear (Model: P19-0023)
510(k) Number:	K230042
Regulation Number	21 CFR 878.4810
Product Code:	OHS, OLP

2) Reference device1

Sponsor:	TRUDERMAL Pro
Device name:	ZLD-390
510(k) Number:	K251012
Regulation Number	21 CFR 878.4810
Product Code:	OHS, OLP, ILY

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 device uses Light Emitting Diode(LED). There are 2 kinds of light mode for the face mask which include Red Light (Red + Near-Infrared), Wavelength: 605nm + 630nm + 660nm + 830nm, Purple Light (Red + Blue light), Wavelength: 630nm+415nm; There is only 1 kind of light mode for the neck mask which include Red Light (Red + Near-Infrared).
There are 3 models of LED Light Therapy Mask which including PE749, PE748, PE756. The product consists of face mask, head straps, mini remote control, USB cable, charging cable, adaptor.
The PE748 is applied directly to the face; The PE759 is applied directly to the skin (include face); The PE756 is applied directly to the skin.
PE748 includes a controller, a face mask and cables; PE756 includes a controller, a neck mask and connecting cables; and PE749 includes a controller, a face mask, a neck mask and two cables.

8. Intended Use:

The LED Light Therapy Mask (Model: PE748) is an Over-the-Counter (OTC) device,

The Red light mode (Red + Near-Infrared light) intended for treatment of wrinkles;

The Purple Light (Red + Blue light) mode intended for mild to moderate inflammatory acne.

The LED Light Therapy Mask (Model: PE749) is an Over-the-Counter (OTC) device,

For the face mask:

The Red light mode (Red + Near-Infrared light) intended for treatment of wrinkles;

The Purple Light (Red + Blue light) mode intended for mild to moderate inflammatory acne.

For the neck mask:

The Red light mode (Red + Near-Infrared light) intended for treatment of wrinkles;

The LED Light Therapy Mask (Model: PE756) is an Over-the-Counter (OTC) device,

The Red light mode (Red + Near-Infrared light) intended for treatment of wrinkles;

9. Predicate Device Comparison

Item	Subject Device	Predicate device 1	Reference device	Comparison Result
Trade name	LED Light Therapy Mask	Q-Rejuvalight Pro Facewear (Model: P19-0023)	TRUDERMAL Pro (ZLD-390)	/
510 (k) number	Applying	K230042	K251012	/
Manufacturer	Duplex International Trading Limited	Light Tree Ventures Europe B.V.	Shenzhen Kaiyan Medical Equipment Co., Ltd.	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810;	Same
Regulation Name	Light Based Over The Counter Wrinkle Reduction, Over-The-Counter Powered Light Based Laser For Acne	Light Based Over The Counter Wrinkle Reduction, Over-The-Counter Powered Light Based Laser For Acne	Light Based Over The Counter Wrinkle Reduction; Over-The-Counter Powered Light Based Laser For Acne; Lamp, Infrared, Therapeutic Heating	Same
Product code	OHS, OLP	OHS, OLP	OHS, OLP, ILY	Same
Classification	II	II	II	Same
Indications for use/ Intended use	The LED Light Therapy Mask (Model: PE748) is an Over-the-Counter (OTC) device, The Red light mode (Red + Near-Infrared light) intended for treatment of wrinkles; The Purple Light (Red + Blue light) mode intended for mild to moderate	The Q-Rejuvalight Pro Facewear (Model: P19-0023) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.	TRUDERMAL Pro (Model: ZLD-390) is an over-the-counter(OTC) device that delivering targeted photo therapy using three wavelengths(blue:415nm, red:630nm, Infrared(IR):850nm): Red light: Reduces full-face wrinkles. Blue light: Treats mild to moderate inflammatory acne. IR light: Provides topical heating for the purpose of elevating tissue temperature, temporarily relieving minor muscle and joint pain, arthritis and muscle spasms; relieving stiffness; promoting relaxation of muscle tissues and temporarily increasing local blood circulation. Mixed lights:	Similar Note1

Item	Subject Device	Predicate device 1	Reference device	Comparison Result
	inflammatory acne. The LED Light Therapy Mask (Model: PE749) is an Over-the-Counter (OTC) device, For the face mask: The Red light mode (Red + Near-Infrared light) intended for treatment of wrinkles; The Purple Light (Red + Blue light) mode intended for mild to moderate inflammatory acne. For the neck mask: The Red light mode (Red + Near-Infrared light) intended for treatment of wrinkles; The LED Light Therapy Mask (Model: PE756) is an Over-the-Counter (OTC)		Red+IR light: Reduces full-face wrinkles. Blue+Red light:Treats mild to moderate inflammatory acne.	

Item	Subject Device	Predicate device 1	Reference device	Comparison Result
	device, The Red light mode (Red + Near-Infrared light) intended for treatment of wrinkles;			
OTC or prescription	OTC	OTC	OTC	Same
Location	Face, Body	Face	Face, Body	
Power supply	Input: 5V⎓2A; Li-ion Polymer Battery: DC 3.7V, 3000mAh, 11.1Wh	Input: 5V, 50/60Hz, 2A Li-ion Polymer Battery: 3.7V, 600mAh, 2.22Wh	Adaptor Input: 100-240Vac, 50-60Hz, 0.8A Output: 12V ⎓ 3A	Similar Note2
Power Source	Li-ion Polymer Battery(rechargeable)	Battery or Universal USB power source	100-240Vac	Same
Light source	LED	LED	LED	Same
Wavelengths	605 nm 630 nm 660 nm 880 nm 415 nm	605 nm 630 nm 660 nm 880 nm 415 nm	Blue: 415±10nm Red: 630±10nm IR: 850±10nm Mixed light: Blue+Red:415nm+630nm Red+IR:630nm+850nm	Same
Power Density	M1-Amber light (605nm) + Red light (630nm) + Dark Red light (660nm) + Near-Infrared light (880nm): 70mW/cm² ± 20% M2- Red light (630nm) + Blue light (415nm): 45mW/cm² ± 20%	wavelength: 605nm: 15±5mW/cm² 630nm: 20±5mW/cm² 660nm: 25±5mW/cm² 880nm: 10±5mW/cm² 415nm: 25±5mW/cm² Total: 70mW/cm²(wrinkle) 45mW/cm²(acne)	Blue:6-10mW/cm² Red:10-15mW/cm² IR:6-10mW/cm² Mixed light: Blue+Red: 16-20mW/cm² Red+IR:16-20mW/cm²	Similar Note4
Treatment time	3 minutes per treatment	3 minutes per treatment	20 min per treatment Acne and Wrinkles:	Same

Item	Subject Device	Predicate device 1	Reference device	Comparison Result
			3-4x weekly; 4 weeks. Pain relief: 3x weekly	
Safety and EMC	IEC 60601-1; IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 662471	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	Similar Note3
Biocompatibility feature	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	Same

Comparison in Detail(s):

Note1

The Indications for use/ Intended use of these five devices are slight difference from each other. They all use LED light in the similar wavelengths to get the intended purpose. The performance of the subject device has been demonstrated by test report. The slight difference will not raise safety and effective issue.

Note2

The power supply of five 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.

Note3

The subject device complies with IEC 60601-2-83 rather than IEC 60601-2-57. The definition Of HOME LIGHT THERAPY EQUIPMENT in IEC 60601-2-83 standard is broader than the corresponding definition of light-source equipment in IEC 60601-2-57 and includes both eye-mediated and skin-mediated photobiological effects, which can be visual and non-visual as explained in the introduction. The definition is restricted to equipment intended to be used. Therefore this difference does not raise new safety concerns for the device.

Note4

1. The M1(Amber light (605nm) + Red light (630nm) + Dark Red light (660nm) + Near-Infrared light (880nm), 70mW/cm² ±20%, 3mins) as same as the Mode(Amber light (605nm) + Red light (630nm) + Dark Red light (660nm) + Near-Infrared light (880nm), 70mW/cm² ±20%, 3mins) of the Predicate device. So, it will not raise safety and effective issue.

2. The M2(Blue light(415nm) + Red light (630nm), 45mW/cm² ± 20%, 3mins) of the subject device`s total power density is lower than the predicate device. However, since the mixed light energy is within the range of the subject and reference device, this will not raise safety nor effectiveness concerns.

10. Performance Data:

Non-clinical data:

Non-clinical tests 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:

- ANSI AAMI ES 60601-1:2005/AMD1:2012/AMD2:2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests
- IEC/TR 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

- IEC 60601-1-11:2015/AMD1:2020, 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 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- IEC 62133-2:2017/AMD1:2021 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
- IEC 62471:2016 Photobiological safety of lamps and lamp systems

Biocompatibility Test

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

- ISO 10993-5:2009, Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2021, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-23:2021, Biological Evaluation of Medical Devices - Part 23: Tests for irritation

Software Verification and Validation Testing

Software verification and validation testing were conducted and basic 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.

The subject device LED Light Therapy Mask is as safe and effective as the legally

marketed predicated devices K230042, K251012.