March 23, 2022

Duplex International Trading Limited
% Doris Dong
Manager
Shanghai CV Technology Co., Ltd.
Room 903, No.19 Dongbao Road, Songjiang Area
Shanghai, Shanghai 201613
China

Re: K214101
Trade/Device Name: Project E Beauty LED Light Therapy Mask (Model: PE730)
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 22, 2021
Received: December 29, 2021

Dear Doris Dong:

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,

Purva Pandya, D.Eng.
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)*
K214101

Device Name
Project E Beauty LED Light Therapy Mask

Indications for Use *(Describe)*
The Project E Beauty LED Light Therapy Mask is an over the counter device that is indicated for the treatment of full face wrinkles and mild to moderate 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

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K214101
Date:	March 16th, 2022
Type of 510(k) Submission:	Traditional 510(k)
Basis for 510(k) Submission:	New device
Owner:	Duplex International Trading Limited B1, 10/F, Block 2, Golden Dragon Ind Centre, 162-170 Tai Lin Pai Road, Kwai Chung, NT, Hong Kong, China Tel: +852-31063608 Email: sales@projectebeauty.com
Contact:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add: Room 903, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris.d@ceve.org.cn Tel: 86 21-31261348 / Fax: 86 21-57712250

2. Device Description

Proprietary Name:	Project E Beauty LED Light Therapy Mask
Model:	PE730
Classification 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
Device Class:	II
Review Panel:	General & Plastic Surgery
Device Description:	The Project E Beauty LED Light Therapy Mask is a facemask-shaped device designed for home-use, which uses Light Emitting Diodes to emit energy in the red, blue and infrared region of the spectrum. The Project E Beauty LED Light Therapy Mask has a total of 36 LEDs. The red light with wavelengths centered at 635-644nm and the infrared light with wavelengths centered at 845-855nm to treat wrinkles on the face. The blue light with wavelengths centered at 430-445nm and the red light with wavelengths centered at 635-644nm to treat mild to moderate acne on the face. The Project E Beauty LED Light Therapy Mask components include the LED module, USB power cord, and integrated module. The user wears the device over the face, like a pair of glasses, and presses the Power button on the integrated module for 1 second to initiate the treatment. The device has a continuous working time of 12 minutes and powers off automatically.
Indications for use:	The Project E Beauty LED Light Therapy Mask is an over the counter device that is indicated for the treatment of full face wrinkles and mild to moderate acne.

3. Predicate Device Identification

Predicate 510(k) Number:	K180856	K180847
Marketing clearance date:	June 19, 2018	June 19, 2018
Product name:	Neutrogena Light Therapy Aging Mask+	Neutrogena Light Therapy Acne Mask+
Manufacturer:	Johnson & Johnson Consumer, Inc.	Johnson & Johnson Consumer, Inc.

4. Substantial Equivalence to Predicate device

Detailed comparison data is included in "Section 10 - Substantial Equivalence Discussion" of this 510(k) submission.

Parameters	**New Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
510(k) number	K214101	K180856	K180847	--
Owner	Duplex International Trading Limited	Johnson & Johnson Consumer, Inc.	Johnson & Johnson Consumer, Inc.	--
Device name	Project E Beauty LED Light Therapy Mask	Neutrogena Light Therapy Aging Mask+	Neutrogena Light Therapy Acne Mask+	--
Model	PE730	/	/	--
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Class	II	II	II	Same
Product code	OHS, OLP	OHS	OLP	Similar
Indication for use	The Project E Beauty LED Light Therapy Mask is an over the counter device that is indicated for the treatment of full face wrinkles and mild to moderate acne.	The Neutrogena Light Therapy Aging Mask+ is an over the counter device that is indicated for the treatment of full face wrinkles.	The Neutrogena Light Therapy Acne Mask+ is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.	
Target population	Individuals with wrinkles and/or mild to moderate acne on the face	Individuals with wrinkles on the face	Individuals with mild to moderate acne on the face	
Location for use	OTC	OTC	OTC	Same
Anatomical site	Full face	Full face	Full face	Same
Type	Mask	Mask	Mask	Same
Irradiance source	LED	LED	LED	Same
Visible light LEDs	Yes	Yes	Yes	Same

LED Array	36 LEDs	No publicly available	12 LEDs	Similar
Light spectrum region	Mode 1: Red +IR light	Red light, IR light	--	Same
	Mode 2: Red +Blue light	--	Red light, Blue light	Same
wavelengths	Mode 1: Red: 635-644nm; IR: 845-855nm	Red: 620-640nm; IR: 820-880nm	--	
	Mode 2: Red: 635-644nm; Blue: 430-445nm	--	Red: 620-640nm; Blue: 425-450nm	
Energy Level	Mode 1: 1.07 mW/cm^2	1.32 mW/cm^2	--	
	Mode 2: 1.75 mW/cm^2	--	2.13mW/cm^2	
Total Energy Dose	Mode 1: 46.24 J/cm^2	47.58 J/cm^2	--	
	Mode 2: 37.87 J/cm^2	--	38.38 J/cm^2	
Treatment Time	Mode 1: 12 minutes/day for 60 sessions	10 minutes/day for 60 sessions	--	
	Mode 2: 12 minutes/day for 30 sessions	--	10 minutes/day for 30 sessions	
Power Supply	Li-Ion rechargeable batteries	Nickel-Metal Hydride rechargeable batteries	Ni-MH Batteries	Similar
Material	ABS, PC, PET	Not publicly available	Not publicly available	
Label and Labeling	Meet FDA's Requirements	Meet FDA's Requirements	Meet FDA's Requirements	Same

4. Non-clinical Testing

The Project E Beauty LED Light Therapy Mask has been evaluated the safety and performance by lab bench testing and conforms to the following international consensus standards:

Electrical safety:

- ANSI AAMI ES60601-1: 2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD);

EMC:

- IEC 60601-1-2 Edition 4.0 2014-02 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests;

Additional safety testing:

- IEC 60601-1-11 Edition 2.0 2015-01 Medical Electrical Equipment -- Part 1-11: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment;
- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems;
- IEC 60601-2-57 Edition 1.0 2011-01 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;
- 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;

Biocompatibility testing:

- ISO 10993-5 Third edition 2009-06-01, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity.
- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

5. Conclusions

The Project E Beauty LED Light Therapy Mask has technological characteristics that are similar to the predicate devices, and when compared to the predicate devices it does not raise new types of questions regarding the safety and efficacy for the above indications for use. Performance testing discussed above was conducted with the device to show that it can perform safely and effectively. The proposed Project E Beauty LED Light Therapy Mask is considered to be substantially equivalent to the predicate devices K180847 and K180856.