February 3, 2025

Shenzhen Ulike Smart Electronics Co., Ltd.
Blue Yang
Official Correspondent
810, Building 1, Xunmei Science and Technology Plaza, No. 8
Keyuan Road, Science Park Community, Yuehai Sub-District, Na
ShenZhen, 518000
China

Re: K243393
Trade/Device Name: JMOON NouvelleSkin Facial Toning Device (M30U PR, M30U MW, M30U SG, M30U SK, M30U MP)
Regulation Numbers: 21 CFR 882.5890; 21 CFR 878.4810
Regulation Names: Transcutaneous Electrical Nerve Stimulator For Pain Relief; Laser Surgical Instrument For Use in General and Plastic Surgery And In Dermatology.
Regulatory Class: Class II
Product Codes: NFO, OHS
Dated: December 27, 2024
Received: December 27, 2024

Dear Blue Yang:

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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine 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.

Submission Number *(if known)*

K243393

Device Name

JMOON NouvelleSkin Facial Toning Device (M30U PR, M30U MW, M30U SG, M30U SK, M30U MP)

Indications for Use *(Describe)*

JMOON NouvelleSkin facial toning device is intended for facial stimulation and indicated for over-the-counter cosmetic use.
JMOON NouvelleSkin facial toning device is an over-the-counter device that emits energy in the red and near-infrared spectrum, designed for the treatment of facial 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.

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510k Summary

This 510(k) Summary is being submitted in accordance with requirements of T itle 21, CFR Section 807.92.

The assigned 510(k) Number: K243393
Date of Preparation: 31/01/2025

1. Information of Submitter and correspondent

Submitter's information

Submitter Name: Shenzhen Ulike Smart Electronics Co., Ltd.
Submitter Address: 810, Building 1, Xunmei Science and Technology Plaza, No. 8 Keyuan Road, Science Park Community, Yuehai Sub-District, Nanshan District, Shenzhen 518000, Guangdong, P.R. China
Establishment Registration Number: 3023339103
Contact Person (including Title): Blue Yang
Tel: +86 15626596120
E-mail: blue@ulike.com

2. Device Identification

- Type of 510(k) submission: Traditional
- Common Name: stimulator, transcutaneous electrical, aesthetic purposes;
- light based over the counter wrinkle reduction
- Trade Name: JMOON NouvelleSkin facial toning device
- Regulation Names: Transcutaneous Electrical Nerve Stimulator For Pain Relief; Laser Surgical Instrument For Use in General and Plastic Surgery And In Dermatology.
- Regulation Medical Specialty: Neurology; General & Plastic Surgery
- Review Panel: Neurology; General & Plastic Surgery
- Product Code: NFO, OHS
- Regulation Numbers: 21 CFR 882.5890; 21 CFR 878.4810
- Regulatory Class: Class II

3. Discussion of Non-clinical test and clinical test for Determination of Substantial Equivalence are as follows:

3.1 Non-clinical testing

A series of safety and performance tests were conducted on the subject device.

- Performance Test
- Biocompatibility test
- Electrical safety
- Home healthcare environment

All the test results demonstrate JMOON NouvelleSkin Facial Toning Device meets the requirements of its predefined acceptance criteria and intended use, and it is substantially equivalent to the predicate device.

3.2 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

4. Predicate Device Information

Sponsor	Heat In A Click	Y & J Bio Co., Ltd
Device Name	2 Face / Face Evolution	easy Claire
510(k) Number	K171821	K213285
Product Code	NFO, OHS, OLP	OHS
Regulation Number	21 CFR 882.5890	21 CFR 878.4810
Regulation Class	Class II	Class II

5. Device Description

Jmoon NouvelleSkin Facial Toning device is an at-home handled device that provides an advanced, easy-to-use and efficient solution for better facial wellness. This device includes microcurrent, red and infra-red light LED, which allow you to customize your treatments according to your face skin. The device provides indicator lights and beeps feedback to guide the user during the treatment cycle.

The microcurrent therapy will deliver 3 different low-level electrical microcurrent impulses on face within a few minutes to complete facial stimulation. The red light

and infra-red therapy is a treatment that uses red light to reportedly improve your skin's appearance, like reducing wrinkles.

6. Indications for Use

JMOON NouvelleSkin facial toning device is intended for facial stimulation and indicated for over-the-counter cosmetic use.
JMOON NouvelleSkin facial toning device is an over-the-counter device that emits energy in the red and near-infrared spectrum, designed for the treatment of facial wrinkles.

7. Test Summary

JMOON NouvelleSkin facial toning device has been evaluated for safety and performance by lab bench testing as follows:

Test Type	Standard	Outcome
Electrical safety	IEC 60601-1 IEC TR 60601-4-2	Conforms
EMC	IEC 60601-1-2	Conforms
Home healthcare environment	IEC 60601-1-6 IEC 60601-2-83 IEC 60601-1-11	Conforms
Safety of Device	IEC 62471 IEC 60601-2-10 IEC 60601-2-57	Conforms
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23	Conforms

8. Substantial Equivalence information

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark S/D
Sponsor	Shenzhen Ulike Smart Electronics Co., Ltd.	Heat In A Click	Y & J Bio Co., Ltd	N/A
Device Name	JMOON NouvelleSkin facial toning device	2 Face / Face Evolution	easy Claire	N/A

Elements of Comparison	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark S/D**
510 (K) Number	Pending	K171821	K213285	N/A
Regulation number	21 CFR 882.5890 21 CFR 878.4810	21 CFR 882.5890	21 CFR 878.4810	N/A
Classification Panel	Neurology, General & Plastic Surgery	Neurology, General & Plastic Surgery	General & Plastic Surgery	N/A
Classification	Class II	Class II	Class II	N/A
Product code	NFO, OHS	NFO, OHS, OLP	OHS	N/A
Indication for Use	JMOON NouvelleSkin facial toning device is intended for facial stimulation and indicated for over-the-counter cosmetic use. JMOON NouvelleSkin facial toning device is an over-the-counter device that emits energy in the red and near-infrared spectrum, designed for the treatment of facial wrinkles	2 Face / Face Evolution is a hand-held device for over-the counter aesthetic purposes. (1) The EMS mode is indicated for facial stimulation; (2) The Photon mode: The red light is intended for the treatment of periorbital wrinkles and the blue light is intended for the treatment of the mild to moderate inflammatory acne.	The easy Claire is an over-the-counter medical device intended for the use in the treatment of full face wrinkles	Difference Note 1
Anatomical Sites	Entire Face	Entire Face	Entire Face	Same
Intended Environment	Home use	Home use	Home use	Same
Type of use	OTC	OTC	OTC	Same
Design	Hand-held device	Hand-held device	Mask	Difference Note 2
Main Unit Weight	210g	200g	Unknown	Difference Note 2
Dimensions of device (inch)	94.4mm*99.6mm*47.8mm	158mm*56mm*51.5mm	Unknown	Difference Note 2

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark S/D
[W x L x D]				
Power source	DC 7.7V 1500mAh	DC 3.7V 2200mAh	Rechargeable lithium-ion battery Adapter： Input :AC 100-240V, 50/60Hz, Output: DC 5V, 2A.	Difference Note 3
For Microcurrent facial stimulation function				
Average DC current through electrodes when device is on but no pulses are being applied	0A	0A	N/A	Same
Number of Output channels	3	2	N/A	Difference Note 4
Regulated Current or Regulated Voltage?	Both	Both	N/A	Same
Software/Firmware /Microprocessor Control?	Yes	Yes	Unknown	Same
Automatic Overload Trip?	Yes	No	Unknown	Difference Note 4
Automatic Shut Off	Yes	Yes	Unknown	Same
Microcurrent Specification				
Waveform and Shape	Pulsed Biphasic, Rectangular	Pulsed Biphasic, Modulated Square	N/A	Difference Note 5
Maximum Output Voltage (specify units)	1.90V±20%@ 500Ω 2.06V±20%@ 1kΩ 2.09V±20%@ 2kΩ 2.16V±20%@ 10kΩ	310mV @ 500Ω 1.16V @ 2kΩ 5.56V @ 10kΩ	N/A	Difference Note 5
Maximum Output Current (specify	3.8mA±20%@ 500Ω 2.06mA±20% @ 1kΩ	620μA @ 500Ω 580μA @ 2kΩ	N/A	Difference Note 5

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark S/D
units)	1.045mA±20%@ 2kΩ 0.216mA±20% @ 10kΩ	556μA @ 10kΩ		
Output Tolerance	+/-20%	+/-10%	N/A	Difference Note 5
Pulse Width (specify units)	LIFT:52us SL: 31/56us EYE:45/56/71/76/82us	60ms	N/A	Difference Note 5
Frequency (Hz)	LIFT: 12.5 Hz SL: 125.0 Hz EYE:50.0Hz	8.333Hz	N/A	Difference Note 5
Maximum Phase Charge (lie)	5.25μC@ 500Ω	26.31μC @ 500Ω	N/A	Difference Note 5
Maximum Current Density (mA/ cm²)	8.84mA/cm²@ 500Ω 4.87 mA/cm²@ 1kΩ 2.47 mA/cm² @ 2kΩ 0.48 mA/cm² @ 10kΩ (The Minimum Electrode Size: 0.31cm²)	0.330mA/ cm² @500Ω (The Minimum Electrode Size: 2.91cm²)	N/A	Difference Note 5
Maximum Power Density (mW/ cm²)	12.11mW/cm²@ 500Ω 7.36 mW/cm²@ 1kΩ 3.78 mW/cm² @ 2kΩ 0.78 mW/cm² @ 10kΩ (The Minimum Electrode Size: 0.31cm²)	4.34μW/ cm² @500Ω (The Minimum Electrode Size: 2.91cm²)	N/A	Difference Note 5
Net Charge (per pulse)	10.50μC @500Ω	Unknown	N/A	Difference Note 6
Time Range (minutes)	EMS Mode (10 minutes)	EMS Mode (5 minutes)	N/A	Difference Note 5
For LED treatment function				
Wavelength	RED (630nm±10nm)	Red (630nm±3nm)	RED (630nm)	Difference Note 7

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark S/D
	IR (855nm±10nm)	Blue (415nm±3nm)	IR (850nm)	
Irradiance	Stamp Mode: Level 1: 18±20% mW/cm² Level 2: 20 ±20%mW/cm² Level 3: 23 ±20%mW/cm² Level 4: 26±20% mW/cm² Level 5: 29±20% mW/cm²	Red light: 73.26 mW/cm²±10% Blue light: 64.10 mW/cm²±10%	20±20% mW/ cm² total	Difference Note 7
Time Range (minutes)	6 minutes	5~7 minutes	9 minutes	Difference Note 7
Additional Features				
Type BF applied part	Type BF applied part	Type BF applied part	Unknown	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	Same
Safety	IEC 60601-1 IEC 60601-1-6 IEC 60601-1-11 IEC 62471 IEC 60601-2-10 IEC 60601-2-57	IEC 60601-1 IEC 60601-2-10 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-6 IEC 60601-1-11 IEC 62471 IEC 60601-2-57	Same
Biocompatibility compliance	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23 ISO 10993-12	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12	Difference Note 8

Comparison in Detail(s):

Note 1:

2 Face / Face Evolution (K171821) as the primary predicate device for EMS function and easy Claire (K213285) as the secondary predicate device for LED function. Ulike finds that the combined the predicate devices 2 Face/Face Evolution (K171821), and easy Claire (K213285) can be substantially equivalent to the subject device per the predicates' 510(k) summary and equivalence discussion. So the differences will not raise any safety or effectiveness issues.

Note 2:

Although the design, appearance and dimensions are different between the subject and predicate devices, these parameters are only related to the product's shape, dimensions and appearance as well as its operation in a home environment. They are not related to any other aspects of safety and/or effectiveness. Ulike provides the IEC testing reports and the testing report shows that the device is compliant with IEC60601-1-11 and IEC60601-1-6. Therefore, these differences will not raise any safety or effectiveness issues.

Note 3:

Although the "Power Supply" is slightly different from that of predicate device and the feature is only related to Electric Safety, it is not related to any safety or effectiveness issues. The lithium battery of the subject device has been tested under standard IEC 62133-2 and has been found to comply with safety standards' requirements of the IEC 60601. Therefore, this slight difference should not raise any safety or effectiveness issues.

Note 4:

Although the number of output channels and Automatic Overload Trip of the subject device are different from the predicate devices, they all comply with the requirements of IEC 60601-1 and IEC 60601-2-10. Therefore, the differences in function specifications will not raise any safety or effectiveness issues.

Note 5:

Though the electrical microcurrent stimulation characteristics of the 2 Face / Face Evolution (including waveform and shape, maximum output voltage, maximum output current, maximum current density, maximum power density, output tolerance, pulse width, frequency, Maximum Phase Charge and time range) are different from the predicate device (K171821).These differences are intended to provide an improved user experience and do not significantly affect the subject device's safety and effectiveness relative to the predicate device (K171821). In particular, the maximum power density meets the maximum allowed value 0.25 (W/cm^2) required in FDA guidance and the timer range of the subject device is close to primary predicate device (K171821). The timer range is based on the intended use, and user can adjust the time and frequency by using the modes described in user manual.

Regarding the maximum output voltage, at 500 Ω and 2k Ω (the most common impedance values), although the output voltage of the tested equipment is higher than that of the equivalent equipment, the maximum output voltage of the tested equipment

1.90V@500 Ω and 2.09V@2k Ω is much lower than the output voltage of 10V specified in clause 201.7.2.101 of IEC 60601-2-10, which is a safe voltage that the human body can withstand.According to FDA approved similar medical device products, such as K220198 approval certificate with a maximum output voltage of 39.3 Vpp @ 500 Ω (+/-20%), K230506 approval certificate with a maximum output voltage of 20Vpp (@ 500Ω), 32Vpp (@ 2kΩ), and 44Vpp (@ 10kΩ), and K221443 approval certificate with a maximum output voltage of 20Vpp (@ 500 Ω), 32Vpp (@ 2kΩ), and 44Vpp (@ 10k Ω), the output voltage of the tested equipment is much lower than the indicators of similar devices mentioned above.

Regarding the output tolerance, the output tolerance of ± 20% set by the tested equipment complies with the provisions of clause 201.12.1.102 in IEC 60601-2-10, which states that "an accuracy of ± 20% is safe enough for therapeutic applications because pulse parameters are set based on subjective patient reactions", and is the same as the product output tolerance specified as+/-20% in the K220198 approval certificate.

Regarding the The current density，The current density of the tested device (e.g. 8.84 mA/cm^2) is similar to that of FDA approved similar medical device products, such as the maximum output current of 8.8mA/cm^2 @ 500 Ω in K221443 approval certificate and 8.8mA/cm2 @ 500 Ω in K230506 approval certificate/ cm2@500 Ω, In response to exceeding the limit of 2 mA/cm2 specified in IEC 60601-2-10, we provide relevant risk analysis content in accordance with clauses 201.4.2 and 201.7.9.2.101g) of IEC 60601-2-10. This is achieved by labeling the equipment and using indicator lights in the corresponding gear positions to ensure compliance with standards and the safety of the equipment and its accessories.

Ulike has provided adequate electrical safety and performance testing, which were conducted according to applicable standards for nerve and muscle stimulators (including IEC 60601-1 and IEC 60601-2-10) as well as lab bench performance evaluation. Therefore, these differences will not any raise safety or effectiveness issues.

Note 6:

The maximum net charge per test is 10.50 μC, which is much lower than the requirement in clause 8.4.3 of IEC 60601-1 that the stored charge should not exceed 45 μC, and similar medical device products approved by the FDA, such as K232001 approval certificate with a net charge of 38.4 μC and K233667 approval certificate with a net charge of 150 μC @ 500Ω. Therefore, the difference in net charge will not affect the safety or effectiveness of the tested device.

Note 7:

The LED "Wavelengths", and "Irradiance" are different from the predicate device (K171821). The subject device use red light (630nm) and IR light (855nm), while the predicate devices (K171821) use red light (630nm) and blue light (415nm). The wavelength of red light of the subject device(630nm) is the same as the predicate device K171821 (630nm), but the Irradiance of the predicate devices (K171821) is greater than the subject device. Therefore, we choose the predicate devices (K213285) as the comparison of LED treatment mode, and the subject device is closer to the predicate devices (K213285).

Although the LED "Wavelengths", and "Irradiance" are a slightly different from the predicate devices (K213285), the wavelength of red light of the subject device(630nm) is the same as the predicate device K213285 (630nm), and the IR light of the subject device (855nm±10nm) is very close to the predicate device K213285 (850nm). The Irradiance of the subject device (including level 1: 18 mW/cm² ; Level 2: 20 mW/cm² ; Level 3: 23 mW/cm² ; Level 4: 26 mW/cm² , Level 5: 29 mW/cm²) is very close to predicate device K213285 (20±20% mW/ cm² total).

They all comply with the IEC 60601-1, IEC 60601-1-2, IEC 60601-2-57, and IEC 62471 safety standards' requirements. Additional HFE report and bench evaluation are performed to ensure its safety and effectiveness. Therefore, these slight differences will not raise any safety or effectiveness issues.

Note 8:

The testing standard of irritation is different. The subject device testing according to ISO10993-23, and while the predicate device is tested according to ISO10993-10 for updating the standard ISO 10993-23, replacing the irritation reaction test in ISO 10993-10.

The differences only pertain to the irritation testing of biocompatibility and do not affect any other performance of safety and/or effectiveness. Ulike has provided the irritation testing report in this submission, which demonstrates the device compliance with ISO 10993-23 for irritation reaction testing. Therefore, the difference will not raise any safety or effectiveness issues.

Comparison to predicate device

The technological characteristics, features, specifications, materials, and intended use of Micro-current function and LED function are substantially equivalent to the predicate devices (K171821 and K213285) quoted above. Even though there is a minor difference in output parameters and construction between the subject device and predicate devices, and the differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Finial Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR part 807 and based on the relative information provided in this premarket notification, we conclude that the JMOON NouvelleSkin Facial Toning Device is substantially equivalent to 2 Face / Face Evolution (K171821) and easy Claire (K213285) with regard to safety and effectiveness.