April 8, 2025

Shenzhen Ulike Smart Electronics Co., Ltd.
Yang Blue
Registration Director
810, Building 1, Xunmei Science and Technology Plaza
No. 8 Keyuan Road, Science Park Community
Shenzhen,
China

Re: K243749
Trade/Device Name: Jmoon Conductive Gel
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive Media
Regulatory Class: Class II
Product Code: GYB
Dated: December 5, 2024
Received: December 5, 2024

Dear Yang Blue:

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)*

K243749

Device Name

Jmoon Conductive Gel

Indications for Use *(Describe)*

JMOON Conductive Gel is intended to be used with microcurrent devices to improve skin conductivity.

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 of K243749

I. Submitter

Shenzhen Ulike Smart Electronics Co.,Ltd.
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
Contact person: Blue Yang
Email: blue@ulike.com
The date the summary was prepared： 12/05/2024

II. Device

Trade Name: Jmoon Conductive Gel
Common Name: Electroconductive Media
Regulation Name: Electroconductive Media
Regulation Number: 21 CFR 882.1275
Product Code: GYB
Review Panel: Neurology

III. Device Description

The Jmoon Conductive Gel is a clear, viscous and chloride-free formulation. The gel is to be applied to the area under an electrode to reduce the impedance of the contact interface between the electrode surface and the skin.

IV. Indications for Use

Jmoon Conductive Gel is intended to be used with microcurrent devices to improve skin conductivity.

V. Comparison of Technological Characteristics With the Predicate Devices

Jmoon Conductive Gel has the same intended use and similar technical characteristics as the predicate device. Any minor differences between the subject device and the listed predicate device do not raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device for its intended use. Therefore, Jmoon Conductive Gel may be found substantially equivalent to its predicate device.

Jmoon Conductive Gel is compared with the following legally marketed devices in terms of intended use, design, and performance:

Items	Subject Device	Predicate Device	Comments
510(k) No.	K243749	K161654	/
Device Name	Jmoon Conductive Gel	NuFACE Gel Primer	/
Regulation Number	882.1275	882.1275	/
Product Code	GYB	GYB	/
Intended Use / Indications for Use	JMOON Conductive Gel is intended to be used with microcurrent devices to improve skin conductivity	The NuFACE Gel Primer is intended to be used with NuFACE microcurrent devices to improve skin conductivity.	Same
Target Population	Adults 18 years of age or older	Adults 18 years of age or older	Same
Environment of Use	Home	Home	Same
Body contact	Intact skin	Intact Skin	Same
Conductive Material	Sodium Salt	Salt (Magnesium Sulfate)	**SE Note 1**
Sterilization	Non-sterile	Non-sterile	Same
Biocompatibility	Complies with ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-23	Complies with ISO 10993-1, ISO 10993-5, ISO 10993-10	Same
Chemical Safety	Non-OSHA PEL	Non-OSHA PEL	Same
pH	5.0 ~ 7.0	6.0 ~ 7.0	**SE Note 2**

Note 1:

Although the conductive material of the subject device is a little different from the predicate device, both of them use the salt. So, the slight difference in pH will not raise any safety or effectiveness issues.

Note 2:

Although the “pH” of the subject device is a little different from the predicate device, both of them are close to the pH value of the human skin surface. So, the slight difference in pH will not raise any safety or effectiveness issues.

Summary of performance testing

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the Jmoon Conductive Gel was conducted in accordance with the "Use of International Standard ISO 10993- 1, 'Biological Evaluation of Medical Devices–Part 1: Evaluation and Testing Within a Risk Management Process, Document", as recognized by FDA. The following testing was performed to, and passed, including:

> 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 skin sensitization
> ISO 10993-23:2021, Biological evaluation of medical devices Part 23: Tests for irritation

2) Shelf-life testing

The shelf life of Jmoon Conductive Gel is 3 years. To ensure the shelf life of Jmoon Conductive Gel, we have performed the accelerated stability testing (3 years). The result demonstrates that the Jmoon Conductive Gel meet intended specification.

3) Performance testing

The results demonstrate that the Jmoon Conductive Gel meet intended performance.

The performance testing conducted on the Jmoon Conductive Gel consisted of the following device characteristics:

Physical, chemical and biological characteristics were evaluated. This included testing for appearance, color, odor, microbiological growth, pH, conductivity, and viscosity. Additional testing evaluated Biocompatibility and packaging and product stability.

Conclusion: Based on the comparison analysis above, the subject device is determined to be Substantially Equivalent (SE) to the predicate device.