May 28, 2026

Guangxi Ulike Medical Technology Co., Ltd.
Blue Yang
Registration Director
Rm. 605, Bldg. 1, Northwest Of Intersection Of Renhou Rd. And Weifang Second Rd., Yulin Traditional Chinese Medicine And Health Industrial Park, Yulin City, Guangxi Zhuang Autonomous Region, China
Yulin, China

Re: K260895
Trade/Device Name: Ulike Clear Zero (YC10 BU)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: March 18, 2026
Received: March 18, 2026

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 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,

Digitally signed by
ZACHARY MCKINNEY -S
Date: 2026.05.28
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for Tushar Bansal, PhD
Acting 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.*

510(k) Number *(if known)*
K260895

Device Name
Ulike Clear Zero (YC10 BU)

Indications for Use *(Describe)*
Ulike Clear Zero is a handheld portable device for over-the-counter aesthetic use including body skin stimulation.

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.***

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# 510(k) Summary of K260895

## I. Submitter

Guangxi Ulike Medical Technology Co., Ltd.

Address: Room 605, Building 1, Northwest of intersection of Renhou Road and Weifang Second Road, Yulin Traditional Chinese Medicine and Health Industrial Park, Yulin City, Guangxi Zhuang Autonomous Region, China

Contact person: Blue Yang

Email: blue@ulike.com

The date the summary was prepared：05/15/2026

## II. Device

Name of Device: Ulike Clear Zero

Model(s): YC10 BU

Common or Usual Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes

Regulation Name: Transcutaneous electrical nerve stimulator for pain relief

Regulatory Class: II

Product Code: NFO

Regulation Number: 21 CFR 882.5890

## III. Device Description

Ulike Clear Zero is a handheld portable device for over-the-counter aesthetic use including body skin stimulation. A digital display on the main unit provides real-time feedback on intensity setting. To operate the device, the user applies the gel to the application area and selects the appropriate mode via the corresponding mode button, then glides the handpiece across the skin. The device incorporates a skin-contact current sensor that only releases electrical energy upon confirmed dermal contact, ensuring safe and effective active infusion throughout the treatment. Upon activation and gel contact, the device emits a voice prompt to indicate the start of treatment and automatically signals completion after six minutes.

## IV. Indications for Use

Ulike Clear Zero is a handheld portable device for over-the-counter aesthetic use including body skin stimulation.

## V. Comparison of Technological Characteristics to the Predicate Devices

The Ulike Clear Zero has the same intended use and similar operational characteristics as the predicate devices. Any minor differences between the subject device and the listed predicate devices do not raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate devices for its intended use. Therefore, the Ulike Clear Zero is substantially equivalent to its predicate devices.

Ulike Clear Zero is compared with the following Predicate Devices in terms of intended use, design, specifications and performance:

| Comparison Items | Subject Device (K260895) | Primary Predicate Device (K233010) | Secondary Predicate Device (K243393) | Remark |
|---|---|---|---|---|
| Trade Name | Ulike Clear Zero | BEAGANK 4T PLUS | JMOON NouvelleSkin facial toning device | / |
| Manufacturer | Guangxi Ulike Medical Technology Co., Ltd. | BELEGA Co., Ltd. | Shenzhen Ulike Smart Electronics Co., Ltd. | / |
| Regulation number | 21 CFR 882.5890 | 21 CFR 882.5890 | 21 CFR 882.5890<br>21 CFR 878.4810 | Same |
| Product code | NFO | NFO | NFO, OHS | Same |
| Device classification | Class II | Class II | Class II | Same |
| Indications for Use / Intended use | Ulike Clear Zero is a handheld portable device for over-the-counter aesthetic use including body skin stimulation. | The BEAGANK 4T PLUS is a handheld portable device for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation. | JMOON NouvelleSkin facial toning device is intended for facial stimulation and indicated for over- | Predicate 1: Same;<br>Predicate 2: Subject device does not |

| Comparison Items | Subject Device (K260895) | Primary Predicate Device (K233010) | Secondary Predicate Device (K243393) | Remark |
|---|---|---|---|---|
| | | | the-counter cosmetic use.<br>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 | include LED feature. |
| Ages | The device is intended for users 18 years of age and older. | The device is intended for users 18 years of age and older. | Adults Only<br>(≥ 22 years of age.) | |
| Prescription or OTC | OTC | OTC | OTC | Same |
| Method of Line Current<br>Isolation | Type BF | Type BF | Type BF | Same |
| Ave. DC current through electrodes when device is on but no pulse are being applied | ＜1μA | ＜1μA | 0A | Same |
| Output Channels | 1 output channel | N/A – 1 output channel | 3 | Same |
| Regulated Current or Regulated | Voltage | Voltage | Both | Same |

| Comparison Items | Subject Device (K260895) | Primary Predicate Device (K233010) | | Secondary Predicate Device (K243393) | Remark |
|---|---|---|---|---|---|
| Voltage | | | | | |
| Automatic Overload Trip | Not required due to circuit design | Not required due to circuit design | | Yes | Same |
| Automatic Shut Off | Yes | Yes | | Yes | Same |
| Patient Override Control | Yes | Yes | | Unknown | Same |
| Sterility | Non-Sterile | Non-Sterile | | Non-Sterile | Same |
| / | / | Mode 4 | Mode 2 | / | / |
| Waveform Shape | Pulsed Biphasic, Modulated Square | Rectangle, biphasic symmetric | Rectangle, biphasic asymmetric | Pulsed Biphasic, Rectangular | Similar<br>Note 1 |
| Max output voltage<br>@500Ω<br>@2kΩ<br>@10kΩ | (+/-20%)<br>5.7V<br>6.5V<br>6.6V | (+/-15%)<br>15.3V<br>21.2V<br>22.9V | (+/-15%)<br>110mV (0.11V)<br>507mV (0.50V)<br>1.87V | (+/-20%)<br>1.90V<br>2.09V<br>2.16V | Similar<br>Note 2 |
| Max output current<br>@500Ω<br>@2kΩ<br>@10kΩ | (+/-20%)<br>11.4mA<br>3.25mA<br>0.66mA | (+/-15%)<br>31.4mA<br>8.60mA<br>2.15mA | (+/-15%)<br>0.45mA<br>0.39mA<br>0.24mA | (+/-20%)<br>3.8mA<br>1.045mA<br>0.216mA | Similar<br>Note 2 |
| Pulse Duration (Cycle) at 500Ω | 300 μs (0.3msec) | 610 μs (0.61msec) | 265 μs (0.265msec) | LIFT: 52 μs<br>SL: 31/56 μs<br>EYE: | Similar<br>Note 2 |

| Comparison Items | Subject Device (K260895) | Primary Predicate Device (K233010) | | Secondary Predicate Device (K243393) | Remark |
|---|---|---|---|---|---|
| | | | | 45/56/71/76/82μs | |
| Frequency | 3.3kHz | 1.64kHz | 3.80kHz | LIFT: 12.5 Hz<br>SL: 125.0 Hz<br>EYE:50.0Hz | Similar<br>Note 2 |
| Net Charge per pulse at 500Ω | 0μC @ 500Ω | 0μC (biphasic symmetrical) | 0.025 μC | 10.50μC @500Ω | Same |
| Max phase charge | 4.08 μC | 0.29 μC | 0.025 μC | 5.25μC @ 500Ω | Similar<br>Note 2 |
| Max current density at 500Ω | 4.45mA/cm2 @500Ω | -Standard: 25.0mA/ cm2<br>-Head: 87.2mA/cm2<br>-Small: 224.3mA/cm2 | -Standard: 0.36mA/ cm2<br>-Scalp: 1.25mA/cm2<br>-Small: 3.21mA/cm2 | 8.84mA/cm²@ 500Ω<br>(The Minimum Electrode Size: 0.31cm²) | Similar<br>Note 2 |
| | | With a wet cotton pad (Purified water)<br>- Standard: 3.13 mA/cm2<br>-Scalp: 10.97 | With a wet cotton pad (Purified water)<br>- Standard: 0.10mA/cm2<br>- Scalp: 0.36 mA/cm2 | | |

| Comparison Items | Subject Device (K260895) | Primary Predicate Device (K233010) | | Secondary Predicate Device (K243393) | Remark |
|---|---|---|---|---|---|
| | | mA/cm2<br>-Small: 28.21<br>mA/cm2 | - Small: 0.92 mA/cm2 | | |
| Max power density at 500Ω (Smallest electrode) | 25.36 mW/ cm² @500Ω | 51775.54 µW/cm2<br>=51.78 mW/ cm² | 17.46 µW/cm2 | 12.11mW/cm²@ 500Ω | Similar<br>Note 2 |
| | | With a wet cotton pad 556.96 µW/cm2 | With a wet cotton pad 33.8 7µW/cm2 | | |
| Treatment recommendation | maximum 6 minutes | 4 modes: maximum 5 minutes each | | EMS Mode (10 minutes) | Similar<br>Note 3 |
| Electrical safety | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-6<br>IEC 60601-1-11<br>IEC 60601-2-10 | IEC 60601-1<br>IEC 60601-1-2 | | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-6<br>IEC 60601-1-11<br>IEC 60601-2-10 | Same |
| Biocompatibility | ISO 10993-5<br>ISO 10993-10<br>ISO 10993-23 | ISO 10993-5<br>ISO 10993-10<br>ISO 10993-23 | | ISO 10993-5<br>ISO 10993-10<br>ISO 10993-23 | Same |

Note 1:

Both waveforms of the subject device and the primary predicate device's mode 4 are symmetric within each pulse, meaning that the positive and negative phases have equal amplitude and equal duration. The subject device maintains the same symmetric charge-balance characteristic as the primary predicate device's mode 4. Therefore, the subject device has the same safety compared to primary predicate device's mode 4.

The "square" shape of the subject device's waveform is electrically equivalent to the "rectangle" shape of the predicate devices – both feature rapid rise time, flat top, and rapid fall time. The addition of modulation (e.g., amplitude modulation, frequency modulation, or pulse width modulation) serves only to reduce tissue adaptation, while operating within the primary predicate's approved operating limits. Therefore, this difference does not raise any new questions of safety or effectiveness.

Moreover, the subject device complies with IEC 60601-1 and IEC 60601-2-10.

Therefore, the waveform difference between the subject device and predicate devices does not raise new questions of safety or effectiveness.

Note 2:
“Max output voltage, “Max output current”, “Pulse Duration”, “Frequency”, “Max phase charge”, “Max current density” and “Max power density” are within the maximum and minimum range of predicate devices. The subject device complies with IEC 60601-1 and IEC 60601-2-10 requirements, so this difference does not raise any new questions of safety or effectiveness.

Note 3:
The treatment time recommendation of the subject device is very close to the primary predicate device. The subject device complies with IEC 60601-1 and IEC 60601-2-10 requirements, so this difference does not raise any new questions of safety or effectiveness.

**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 Ulike Clear Zero 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 10993-10:2021, 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.
- ISO 10993-5: 2009, Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity.

2) Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing was performed to, and passed, as per the following standards:

- IEC 60601- 1:2005+A1:2012+A2:2020 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 60601- 1- 11:2015+A1:2020 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 60601-2-10:2012+A1:2016+A2:2023 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.

3) Software Verification and Validation

Software documentation consistent with Basic Documentation Level was submitted in this 510(k). System testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

4) Performance Testing – Bench

The device performance was verified by evaluating the following technical capabilities of the device:

- Output Voltage
- Net Charge

- Output Current
- Pulse Duration
- Frequency
- Phase Charge
- Current Density
- Power Density

The results of the verification tests met the internal prespecified acceptance criteria and did not raise different questions of safety or effectiveness.

5) Usability

The product usability has been evaluated and validated according to the following standard:

- IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

**Conclusion**

The Ulike Clear Zero has the same intended use as the predicate devices. The differences in technological characteristics do not raise different questions of safety and effectiveness, and the performance data demonstrate that the Ulike Clear Zero is substantially equivalent to the cleared predicate devices.