May 8, 2026

El Global Trade Ltd.
Stephanie Khoury
RA/QA Associate
Gibore Israel 13
Netanya, 42407
Israel

Re: K252621
Trade/Device Name: DeepSkin (DEP100)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: April 9, 2026
Received: April 9, 2026

Dear Stephanie Khoury:

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,

Tushar Bansal -S

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.

Submission Number *(if known)*

K252621

Device Name

Microcurrent Device (model number: DEP100)

Indications for Use *(Describe)*

The Microcurrent Device (Model: DEP100) is intended for facial stimulation for over-the-counter cosmetic use.

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.

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"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."

K252621 510(K) Summary
EL Global Trade Ltd. For DEP100

1. DATE PREPARED: April 9th, 2026

2. 510(K) OWNER NAME

EL Global Trade Ltd.
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Tel: +972-9-7889069 Fax: +972-9-7734831

Contact person name:
Sivan Fishman, VP Global Compliance
Phone: +972-54-5223677
E-mail: sivanf@sensica.com

3. DEVICE NAME

Common/Usual Name: Microcurrent Device

Model Name: DEP100

Classification: **Class II** device under the following classification names:

Classification Name	Product Code	Regulation Number	Panel
Transcutaneous electrical nerve stimulator for pain relief	NFO	882.5890	Neurology

4. PREDICATE DEVICES

Facial Spa device by Nu Skin Enterprises Inc.

Cleared under 510(k) number **K122711** on September 17th, 2013.

5. DEVICE DESCRIPTION

The *DEP100 device* is an OTC, home-use hand-held battery-powered device used with FDA cleared conductive gel to stimulate the face with microcurrents. The device is intended for facial stimulation for OTC cosmetic use. It is a non-invasive, non-ablative device consisting of:

- User Interface
- Programmable logic controller (PLC, microcontroller) embedded in PCBA
- Microcurrent power module
- Power Supply
- Microcurrent electrodes

The PLC (on the PCBA) is specially configured software that, combined with hardware circuits, provides the operational and safety function of the system. The Microcurrent power module provides microcurrent to the active tip electrodes. This device is supplied non-sterile.

6. INDICATIONS FOR USE:

The *DEP100 device* is indicated for facial stimulation for over-the-counter cosmetic use.

7. INTENDED USE:

The *DEP100 device* is an over-the-counter home-use device intended for the stimulation of healthy facial skin.

8. NON-CLINICAL (BENCH)PERFORMANCE DATA

The following performance data (bench tests) were provided in support of the performance, safety, and efficacy of the *DEP100 device* as well as the substantial equivalence determination.

Safety Bench Tests and Verification & Validation (V&V) Summary

The device was internally tested for V&V as per pre-determined device requirements and specifications.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the DEP100 device. The device complies with:

- IEC 60601-1:2005/EN 60601-1:2006, General safety standard: safety requirements for medical electrical systems.
- IEC 60601-1-2:2014/EN 60601-1-2:2015, Medical electrical equipment Part 1-2 - General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
- IEC 60601-1-11:2015, Medical electrical equipment Part 1-11 – Requirements for the medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 60601-2-10: 2012, Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff. "Guidance for the Content of Premarket Submissions for Device Software Functions." The document level for this software was considered "Basic".

Human Factors Validation Testing

The human factors and usability validation of the DEP100 device are based on:

1. IEC 60601-1-6:2010 test report
2. A self-selection and human factors validation study

A Self-Selection and Human Factors validation study was performed to demonstrate that users can safely and effectively self-select, prepare and perform treatment with the DEP100 device.

The Self-Selection study proved the self-selection of the users, reaching El Global's goal. 18 subjects who successfully self-selected themselves as eligible for treatment with the device, performed treatment with the DEP100 device using the device labeling and IFU. The users participating reached a validation rate of 100% success rate for all critical tasks, with no critical issues raised during use. These results demonstrated that the design of the DEP100 device is safe for use by the intended lay users.

9. PERFORMANCE TESTING – ANIMAL

No animal testing was performed with the subject device.

10. CLEANING, STERILIZATION, SHELF LIFE AND BIOCOMPATIBILITY

The DEP100 device is a non-sterile, reusable device, intended for a single user. The device cleaning instructions are based on the cleaning instructions of the predicate device due to the fact that both devices are made of the same materials and used similarly.

The shelf-life expectancy of the device is 5 years, similarly to the predicate device.

The biocompatibility evaluation for the DEP100 device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" September 4, 2020, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1:

Evaluation and Testing Within a Risk Management Process," as recognized by FDA.
In the case of a device with such a classification, the prerequisite information for the risk assessment is the physical and/or chemical information (in accordance with ISO 10993-18). Additional endpoints required for this classification in case of missing or insufficient information are Cytotoxicity, Sensitization and Irritation.

Components of the DEP100 device were tested in accordance with REACH and RoHS standards in order to confirm that no dangerous or toxic materials are present in the device composition. Additionally, the materials used in the manufacture of the device are materials commonly used in the medical device industry. These materials are also used in the manufacturing process of El Global Trade Ltd.'s devices, for which Cytotoxicity, Irritation, and Sensitization tests were performed.

11. CLINICAL PERFORMANCE DATA

No clinical testing was gathered for the subject device, as it is substantially equivalent to the predicate device, and thus requires no additional clinical data to prove its safety and efficacy.

12. SUBSTANTIAL EQUIVALENCE

The indications for use and technological characteristics of the DEP100 device are substantially equivalent to the indications for use and technological characteristics of the predicate device, as can be seen in the technology comparison table below.

The design and components of both devices (i.e., power supply, Micro-current generator, and controller) are similar. The performance specifications of the DEP100 (i.e., Micro-current and electrical power) are substantially equivalent to those of the predicate device. The safety features and compliance with safety standards of both are similar. The body contact materials

are similar. The minor differences in the technological characteristics do not raise new safety or effectiveness concerns and are demonstrated to be substantially equivalent through relevant performance tests. Furthermore, the DEP100 device has qualified with varied performance tests, including software validation testing, electrical and mechanical safety testing according to IEC 60601-1, electromagnetic compatibility testing according to IEC 60601-1-2, compatibility as medical electrical equipment for home healthcare environment according to 60601-1-11, and basic safety and essential performance of nerve and muscle stimulators according to IEC 60601-2-10. The performance tests demonstrated that the device specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Feature	***DEP100*** (EL Global Trade LTD) **Subject Device**	***Facial Spa*** (Nu Skin Enterprises, Inc.) [K122711] **Predicate Device**
Device Class	Class II	Class II
Product Code	NFO	NFO
Regulation Number	21 CFR 882.5890	21 CFR 882.5890
Device	Stimulator, Transcutaneous Electrical, Aesthetic Purposes	Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Regulation Description	Transcutaneous Electrical Nerve Stimulator	Transcutaneous Electrical Nerve Stimulator
Review Panel	Neurology	Neurology
Indication for Use	Over-the-counter cosmetic use	Over-the-counter cosmetic use
Intended Use	The device is intended for facial stimulation for over-the-counter cosmetic use.	The device is intended for facial stimulation for over-the-counter cosmetic use.
Intended User Population	OTC device. General population – healthy adults, treatment on intact skin (according to contraindications).	OTC device. General population – healthy adults, treatment on intact skin (according to contraindications).
Intended Treated / Application Site	Face	Face
Principle of Operation	Non-invasive, one hand operation, based on micro-current.	Non-invasive, one hand operation, based on micro-current.

Feature	*DEP100* (EL Global Trade LTD) **Subject Device**	*Facial Spa* (Nu Skin Enterprises, Inc.) [K122711] **Predicate Device**
	To be used with prior applied conductive gel.	To be used with prior applied conductive gel.
Treatment Duration	5-10 minute treatment depending on the area.	5-10 minute treatment depending on the area.
Technology	Micro-current device	Micro-current device
Waveform	Direct current	Direct current
Maximum Average Output Voltage	~200 mV @ 500 Ω ~800 mV @ 2 KΩ ~4 V @ 10 KΩ	~200 mV @ 500 Ω ~800 mV @ 2 KΩ ~4 V @ 10 KΩ
Maximum Output Current	~400 µA @ 500Ω ~400 µA @ 2kΩ ~400 µA @ 10kΩ	~400 µA @ 500Ω ~400 µA @ 2kΩ ~400 µA @ 10kΩ
Charge Per Phase	N/A – no phases. The current flows in one direction.	N/A – no phases. The current flows in one direction.
Average DC when the device is ON, but no pulse is applied	0	0
Number of Output Channels	1	1
Software/ Microprocessor Control	Yes	Yes
Automatic No-Load Trip	Yes	Yes
Automatic Shut-Off	Yes	Yes
User Over-ride Control	Yes	Yes
Low Battery Display Indicator	Yes	Yes
Voltage/Current Level Indicator	No	No
Device Main Components	Hand-held handpiece, two treatment surfaces, power adaptor, conductive gel in cartridge.	Hand-held handpiece, two treatment surfaces, power adaptor, conductive gel.
Power Source	Battery operated – Rechargeable Li-ion battery	Battery operated – two AAA Alkaline batteries
Main unit weight	120gr (4 oz)	120 gr (4 oz)
Main unit size	19.3 × 6.4 × 4.9 [cm^3]	With large conductor: 14.3 × 3.12 × 6.75 [cm^3] With small conductor: 13.6 × 3.12 × 6.75 [cm^3]

Feature	*DEP100* (EL Global Trade LTD) **Subject Device**	*Facial Spa* (Nu Skin Enterprises, Inc.) [K122711] **Predicate Device**
Electrodes size	Large conductor: ~22 cm^2 Small conductor: ~2 cm^2	Large conductor: ~8.3 cm^2 Small conductor: ~2.4 cm^2
Maximum Average Current Density (@ 500 Ω)	Large conductor: ~18 $\mu A/cm^2$ Small conductor: ~200 $\mu A/cm^2$	Large conductor: ~48 $\mu A/cm^2$ Small conductor: ~160 $\mu A/cm^2$
Contact (electrodes) material	Chrome plated ABS	Chrome plated ABS
Safety/ EMC	**IEC 60601-1:2005 (Ed. 3.1)**, Medical Electrical Equipment - Part 1: General safety standard safety requirements for medical electrical systems. **IEC 60601-1-2: 2014 (Ed. 4),** Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements And Tests. **IEC 60601-2-10:2012 (Ed. 2),** Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators. **IEC 60601-1-11:2015 (Ed. 2)**, Medical electrical equipment Part 1-11 – Requirements for the medical electrical equipment and medical electrical systems used in the home healthcare environment.	**IEC 60601-1:1998 (Ed. 2)**, Medical Electrical Equipment - Part 1: General safety standard safety requirements for medical electrical systems. **IEC 60601-1-2: 2012 (Ed. 3),** Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements And Tests. **IEC 60601-2-10:1987 (Ed. 1),** Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.
Biocompatibility	All parts that are in contact with user comply with the requirements of ISO-10993-1.	All parts that are in contact with user comply with the requirements of ISO-10993-1.

Feature	***DEP100*** (EL Global Trade LTD) **Subject Device**	***Facial Spa*** (Nu Skin Enterprises, Inc.) [K122711] **Predicate Device**
Software	The software was verified and validated according to the FDA guidance.	**IEC 60601-1-4:1996 (Ed. 1.1),** Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems
Compliance with 21 CFR 898	Yes	Yes

The DEP100 device is substantially equivalent to the predicate device, as the devices share a common intended use, and technological differences between the DEP100 device and the predicate do not raise new questions of safety or effectiveness.

13. CONCLUSIONS

Due to these identical clauses and high similarities, the DEP100 device is at least as safe and as effective as the predicate device, since they share the same intended use, technological characteristics, features, specifications, materials, and anatomical site for use. The differences between the DEP100 device and the predicate device do not raise new safety or effectiveness issues or questions, as detailed above. Based on performance testing and comparison to predicate devices, the DEP100 device is substantially equivalent to the previously cleared Facial Spa predicate device.