December 21, 2022

Andon Health Co., Ltd.
Liu Yi
President
No. 3 Jinping Street, Ya An Road, Nankai District
Tianjin 300190
P.R. China

Re: K222867
Trade/Device Name: AD-2126 Transcutaneous Electrical Nerve Stimulators (TENS)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NYN
Dated: September 22, 2022
Received: September 22, 2022

Dear Mr. Liu Yi:

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,

Robert M. Stefani -S

Digitally signed by Robert M. Stefani -S
Date: 2022.12.21 11:44:22 -05'00'

For Pamela Scott
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
AD-2126 Transcutaneous Electrical Nerve Stimulators (TENS)

Indications for Use *(Describe)*
The AD-2126 Transcutaneous Electrical Nerve Stimulators TENS device is intended for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities, It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

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

(In accordance with 21 CFR 807.92)

1.0 Submitter's Information

Name:	Andon Health Co., Ltd.
Address:	No 3, Jinping Street, Ya An Road, Nankai District, Tianjin, 300190, P.R. China
Phone Number:	86-22-87611660
Fax Number:	86-22-87612379
Contact:	Mr. Liu Yi
Date of Preparation:	September 19, 2022

2.0 Device Information

Device Name:	AD-2126 Transcutaneous Electrical Nerve Stimulators (TENS)
Classification Name:	Stimulator, Nerve, Transcutaneous, Over-The-Counter

3.0 Classification

Product Code:	NUH, NYN
Regulation Number:	21 CFR 882.5890
Classification:	II
Review Panel:	882 Neurology

4.0 Predicate Device Information

Manufacturer:	Andon Health Co., Ltd.
Device:	AD-2126 Transcutaneous Electrical Nerve Stimulators (TENS)
510(k) Number:	Kl50043
Classification	II
Product Code	NUH, NYN

5.0 Intended Use

The AD-2126 TENS device is intended for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities. It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

6.0 Device Description

The AD-2126 Transcutaneous Electrical Nerve Stimulators (TENS) is transcutaneous electrical nerve stimulator for relief of muscular pain and sold without prescription.

The device consists of a microprocessor, buttons, electrical pads, and display. Keys can control the device to choose the operation modes, adjust pulse output strength, then the channel that effectively transfers your desired choice of programmed electrical pulses directly through electrode adhesive pads to the suggested area of the body where the electrodes are placed, causing minimal muscle stimulation. The LCD display can show user the mode and strength chosen and other information.

Self-adhesive electrodes are used in this device, and they are designed with conductive adhesive interface between the patient's skin and the Electrical Stimulator which help electrical signals transferred from the TENS device to the body and complete its function. The electrodes to be used with the device have been cleared under submission number K130987 with the trade name of ValuTrode® Neurostimulation Electrodes; model number: 50X50.

7.0 Discussion of Non-Clinical Testing

TENS conforms to the following standards:

- AAMI ANSI ES60601-l:2005/(R)2012 And Al:2012, Cl: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)
- 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 systems used in the home healthcare environment
- IEC 60601-2-10 Edition 2.1 2016-04, Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 60601-1-2:2014, Medical Electrical Equipment Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
- ISO 10993: Biological evaluation of medical devices Part **1:** Evaluation and testing within a risk management process.
- ISO 10993: Biological evaluation of medical devices Part 5: Test for in vitro cytotoxicity.

- ISO 10993: Biological evaluation of medical devices Part 10: Test for irritation

and skin sensitization.

None of the test demonstrate that the new device raises new questions of safety and effectiveness as compared to the predicate.

8.0 Non-clinical Testing Summary

The following testing was performed on the TENS devices in accordance with the requirements of the design control regulations and established quality assurance procedures.

(1) Biocompatibility of materials

When use the TENS device, one side of the electrode will contact the user, and the materials used on this side is tested according to ISO 10993-5 and ISO 10993-10, and the result shows it meet the applicable requirements.

(2) Electromagnetic Compatibility

Electromagnetic Compatibility test has been performed on the TENS devices according to the identical standard of lEC 60601-1-2, and the test result show that, the device meets all the applicable requirements.

(3) Electrical Safety Testing

Electrical Safety Test has been performed according to AAMI ANSI ES60601-1, and the test result shows that, the device meets all the applicable requirements. Also, particular safety test has been performed according to IEC 60601-2-10.

9.0 Comparison to the Predicate Device and Conclusion

The conclusion drawn from the nonclinical tests demonstrate that the subject device AD-2126 Transcutaneous Electrical Nerve Stimulators is substantially equivalent to theAD-2129A Transcutaneous Electrical Nerve Stimulators (Kl50043).

Characteristics	Subject device	Predicate device	Comparison
Product name	AD-2126 TENS device	AD-2129A TENS device	
510(K)number	To be assigned	Kl50043	
Product code	NUH,NYN	NUH,NYN	Same
Regulation No.	21 CFR 882.5890	21 CFR 882.5890	Same
Intended use	The device is intended for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household	The device is intended for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household	Same

	and work activities, It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.	and work activities, It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.	
Presentation or OTC	OTC	OTC	Same
Environment of use	Home use	Home use	Same
Number of Outputs mode	24	8	See 3.3 Note 1
Number of Outputs	2	2	Same
Waveform	Biphasic rectangular Monophasic rectangular	Asymmetrical Biphasic rectangular	See 3.5 Note2
Maximum output voltage(max) 500Ω, 2 k Ω, and 10 k Ω	500 Ω: 60V 2K Ω:64.8V lOK Ω: 68.4V	500 Ω: 48V 2K Ω : 91.2V 10 k Ω: 46V	See 3.6 Note 3
Maximum OutputCurrent 500Ω, 2 k Ω, and 10 k Ω	500Ω: 120mA 2K Ω: 32.4mA 10K Ω: 6.84mA	500 Ω: 96mA 2K Ω: 4.33mA 10 k Ω:0.44 mA	See 3.6 Note3
Maximum Phase Charge, (μC) @ 500Ω	12uC	13.82uC	See 3.6 Note3
Maximum Average Current(500Ω)	8.49mA	l.0mA	See 3.6 Note 3
Maximum Current Density, (mA/cm² @500Ω)	0.34mA/cm²	0.39mA/cm²	See 3.6 Note 3
Maximum Average Power Density, (W/cm²@500Ω	l.44mW/cm²	l.66mW/cm²	See 3.6 Note 3
Frequency (Hz)	1-l00Hz	2-125HZ	See 3.6 Note 3
Pulse Duration(us)	1-100	60-120	See 3.6 Note 3
Burst Mode	None	None	Same
Timer range(min)	15~30 minutes can be set for all programs(The default value is 15 minutes)	15 minutes for all programs	See 3.8 Note4
Indication display:	-On/Off status -Low battery	-On/Off status -Output strength	See 3.9 Note 5

	-Voltage/Current level -Output mode -Time to cut-off	-Output mode -Time to cut-off	
Power Source	4x 1.5 size AAA ⎓	4x1.5 size AAA ⎓	Same
Dimension	120.3mmx60.3mmx20.6mm	140mmx63mmx30mm	See 3.11 Note6
Weight	73g (exclude battery)	88g (exclude battery)	See 3.11 Note6
Housing Materials	ABS	ABS	Same
Microprocessor control	Yes	Yes	Same
Automatic Overload trip	No	No	Same
Automatic no-load trip	Yes	Yes	Same
Automatic shut-off	Yes	Yes	Same
User override control	No	No	Same
Electrode compliance with 21 CFR 898	Yes	Yes	Same
Electrode cable	Yes	Yes	Same

Note: For the Maximum Average Power Density: Surface area: S=25 cm^2; maximum average current output: 1=8.49mA; Load: R=500Ω; power density: P= I*I*R/S=0.00144(watts/cm^2)

1. **Note 1** The number of output mode of the new device is changed, EMC test, Electrical Safety test and particular safety test have been performed on the new device, and the result show that, the new device is the same safe and effective as the predicate device.

2. **Note 2** The waveform of the new device AD-2126 is different from the predicate device, they all have the Biphasic rectangular waveform. EMC test, Electrical Safety test and particular safety test have been performed on the new device, and the result show that, the new device is the same safe and effective as the predicate device.

3. **Note 3** The output specification are different from the predicate device, such as the Maximum output voltage (at 500Ω, 2 k Ω, and 10 k Ω), the Maximum Output Current (at 500Ω, 2 k Ω, and 10 k Ω), the Maximum Phase Charge(at 500Ω), the Maximum Average Current(at 500 Ω), the Maximum Current Density(at 500Ω) and the Maximum Average Power Density(at 500Ω). Moreover, the frequency and time

duration are also changed. However, the Electrical Safety test and particular safety test can conform that, they are the same safe and effective.

4. Note 4 15-30 minutes timer range can be set for all programs, which is different from the predicate device, but the software validation can confirm that, the new device is the same safe and effective as the predicate device.

5. **Note 5** The indication display of the new device is the changed, but the software validation can confirm that, the new device is the same safe and effective as the predicate device.

6.Note 6 The dimension and weight are different, because the appearance of the device is changed, however, the Electrical test report and the EMC test report for the new devices can confirm that they are the same safe and effective as the predicate device.

However, the tests in this submission demonstrates that these small differences do not raise any new questions of safety and effectiveness.