December 15, 2021

Top-Rank Health Care Co., Ltd.
% Yuling Chen
Official Correspondent
Microkn Business Consulting (Shanghai) Co., Ltd.
Room 1219, Block A, No3699, Gonghexin Road, Jingan District
Shanghai, Shanghai 200040
China

Re: K210223
Trade/Device Name: Transcutaneous Electrical Nerve Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: November 24, 2020
Received: January 28, 2021

Dear Yuling Chen:

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,

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)*
K210223

Device Name
Transcutaneous Electrical Nerve Stimulator

Indications for Use *(Describe)*
The TOPTENS-01 can be used for the Symptomatic relief of chronic intractable pain, Post traumatic pain adjunctive treatment, Post-surgical pain adjunctive treatment.

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

Product name	Transcutaneous Electrical Nerve Stimulator
Model	TOPTENS-01
Applicants	Top-Rank Health Care Co.,Ltd.
Document Name	510(k) Summary
Objective	510 (k) Application

510(k) Summary

1. Contact information

1.1. Applicant

Applicant Name: Top-Rank Health Care Co.,Ltd.

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1.2. Consultant

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2. Device information

- Trade Name: Transcutaneous Electrical Nerve Stimulator
- Model(s): TOPTENS-01
- Classification: II
- Product Code: NUH
- Regulation Number: 21 CFR 882.5890
- 510（K）Number: K210223

3. Indications for Use

- Symptomatic relief of chronic intractable pain
- Post traumatic pain adjunctive treatment
- Post surgical pain adjunctive treatment

4. Legally Marketed Predicate Device

Product name:Transcutaneous Electrical Nerve Stimulator (T.E.N.S)

510(k) Number: K152374

Product Code: NUH

Manufacture: Fuji Dynamics Ltd

5.Description of the device

The proposed device is transcutaneous electrical nerve stimulator for pain

relief. this is a device used to apply an electrical current to electrodes on a patient's skin to treat pain. It only has one model: TOPTENS-01.

TOPTENS-01 is mainly composed: host, built-in power supply, output lead and electrode.

TOPTENS-01 power supply is DC4.5V, using built-in removable 3 AAA batteries.

TOPTENS-01 comes with 2 independent output channels (A&B). Users can be adjust independently the two output channels Intensity by pressing the Left and right sides Intensity adjustment key.

LCD screen display the remaining stimulation time in the top left corner. The default stimulation time is 30 minutes

TOPTENS-01 has 9 types stimulation modes: Mode1, Mode2, Mode 3, Mode 4, Mode 5, Mode6, Mode 7, Mode 8, Mode 9. These stimulation modes can be selected by pressing the <P> key.The detailed difference shown in Table 1.

Table 1 the Difference of Models

Mode	Frequency (Hz)	Pulse Width (μs)	Max amplitude (V)(Vpeak, @500Ω)	Output Mode	Position for Use
Mode 1	60～100	100～150	33	Frequency Modulation & Pulse Width	Back of Neck

Table 1 the Difference of Models					
Mode	Frequency (Hz)	Pulse Width (μs)	Max amplitude (V)(Vpeak, @500Ω)	Output Mode	Position for Use
				Modulation	
Mode 2	80～100	260	23	Frequency Modulation	Shoulder
Mode 3	100～150	100	33	Frequency Modulation	Lumbar pain
Mode 4	100	100	23	Continuous wave	Elbow
Mode 5	120	100～150	33	Pulse Width Modulation	Knee
Mode 6	100～150	200	23	Frequency Modulation	Hip
Mode 7	100	260	23	Continuous wave	Elbow 2
Mode 8	100	100	33	Continuous wave	Knee 2

Table 1 the Difference of Models					
Mode	Frequency (Hz)	Pulse Width (μs)	Max amplitude (V)(Vpeak, @500Ω)	Output Mode	Position for Use
Mode 9	60～100	100～160	33	Frequency Modulation & Pulse Width Modulation	Back of Neck 2

Note 1: Do not place the electrodes on the Spine.

Note 2: Do not place the electrodes directly over joints.

The main components of proposed device shown in **Table 2**.

Table 2 Main Components of Proposed Device	
Components	Function Description
Host	Control circuit signal, user interface, key interaction
Built-in power supply	Energy Supply
Pads	Is responsible for sending electrical signals to the skin
Set of Lead Wires	Is responsible for transmitting electrical signals to the Pads

6.Non-Clinical Test conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-2-10:2016, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
- ANSI/AAMI/ES 60601-1: 2005/(R)2012 and A1:2012, C1:2009/(r)2012 and a2:2010/(r)2012. Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-1-11-2015 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 60601-1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic disturbances-Requirements and tests. The EMC property meets the requirements.

7.Clinical Test Conclusion

No clinical study is included in this submission.

8.Predicate Devices

Product name:Transcutaneous Electrical Nerve Stimulator (T.E.N.S)

510(k) Number: K152374

Product Code: NUH

Manufacture: Fuji Dynamics Ltd

9.Substantially Equivalent (SE) Comparison

The Transcutaneous Electrical Nerve Stimulator has been carefully compared to legally marketed devices with respect to intended use, configuration, principle of operation **(Table 3)**, and performance specifications **(Table 4).**

Table 3 General Comparison

Item	**Proposed Device**	**Predicate Device**	**Remark**
	TOPTENS-01	**Transcutaneous Electrical Nerve Stimulator (T.E.N.S)**	
Product Code	NUH	NUH	Same
510(k) Number	K210223	K152374	--
Regulation	21 CFR 882.5890	21 CFR 882.5890	Same

Table 3 General Comparison			
Item	**Proposed Device**	**Predicate Device**	**Remark**
	TOPTENS-01	**Transcutaneous Electrical Nerve Stimulator (T.E.N.S)**	
Number			
Indications for Use	● Symptomatic relief of chronic intractable pain ● Post traumatic pain adjunctive treatment ● Post surgical pain adjunctive treatment	Used for the symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.	Same
Principle of Operation	The device applies low-frequency current to human tissue through the body surface skin, and treats specific parts of the human body through the generated electrochemical and electrophysiological reactions.	The device applies low-frequency current to human tissue through the body surface skin, and treats specific parts of the human body through the generated electrochemical and electrophysiological reactions.	Same

Table 3 General Comparison			
Item	**Proposed Device**	**Predicate Device**	**Remark**
	TOPTENS-01	**Transcutaneous Electrical Nerve Stimulator (T.E.N.S)**	
Type of use	OTC	OTC	Same

Table 4 Performance Comparison

Table 4 Performance Comparison			
Item	**Proposed Device**	**Predicate Device**	**Remark**
	TOPTENS-01	**Transcutaneous Electrical Nerve Stimulator (T.E.N.S)**	
Power source	DC 4.5V, 3 AAA batteries	DC 3.0V, 2 AAA batteries	Difference 1
- Method of Line Current Isolation	Type BF	Type BF	Same
- Normal condition	2μA	-	Difference 1
- Single fault condition	N/A	N/A	Same
User interface	By LCD display	By LCD display	Same

Table 4 Performance Comparison			
Item	**Proposed Device**	**Predicate Device**	**Remark**
	TOPTENS-01	**Transcutaneous Electrical Nerve Stimulator (T.E.N.S)**	
Number of output models	4	4	Same
Output channel	Two channels	Two channels	Same
Number of output models	1	1	Same
Number of output channels	2	2	Same
Number of anatomical locations	6	6	Same
Anatomical locations	Back of Neck , Shoulder, Lumbar pain, Elbow, Knee, Hip	Back of Neck, Shoulder, Lumbar pain, Elbow, Knee, Hip	Same
-Synchronous or Alternating?	Synchronous	Alternating	Difference 2
-Method of channel isolation	By enclosure	By enclosure	Same

Table 4 Performance Comparison			
Item	**Proposed Device**	**Predicate Device**	**Remark**
	TOPTENS-01	**Transcutaneous Electrical Nerve Stimulator (T.E.N.S)**	
Regulated Current or Regulated Voltage?	Regulated Voltage	Regulated Voltage	Same
Software/Firmware/ Microprocessor Control?	Software	Software	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
Indication Display	—	—	—
-On/off status?	Yes	Yes	Same
-Low battery?	Yes	Yes	Same

Table 4 Performance Comparison			
Item	**Proposed Device**	**Predicate Device**	**Remark**
	TOPTENS-01	**Transcutaneous Electrical Nerve Stimulator (T.E.N.S)**	
-Voltage/ current level?	Yes	Yes	Same
Time range (min)	5～60 minutes (5,10,15,20,25,30,35,40, 45,50,55and 60 min selectable)	Continuous, 15 min, 30 min, 45 min and 60 min selectable.	Difference 3
Compliance with Voluntary Standards?	Yes. AAMI/ANSI ES 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	Yes. AAMI/ANSI ES 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	Same
Compliance with 21 CFR 8988?	Yes	Yes	Same
Weight（lbs.）	0.18 (Battery Excluded)	70g	Difference 4
Dimensions(in.) [W × H × D] For unit	2.32x 4.96x1.18	38x127x20	
Housing materials	Plastic (ABS) enclosure	ABS	

Table 4 Performance Comparison			
Item	**Proposed Device**	**Predicate Device**	**Remark**
	TOPTENS-01	**Transcutaneous Electrical Nerve Stimulator (T.E.N.S)**	
construction			
Waveform	biphasic symmetrical Square waveform	biphasic symmetrical Rectangular waveform	Same
Shape	Square	Square	Same
Maximum output voltage (Vp)	33 @500Ω	70 @500Ω	
	60 @2kΩ	98 @2kΩ	
	100 @10kΩ	108 @10kΩ	Difference 5
Max Output Current (mA)	66 @500Ω	140 @500Ω	
	30 @2kΩ	49 @2kΩ	Difference 5
	10 @10kΩ	10.8 @10kΩ	
Pulse Width Range(uS)	100～260	104	Difference 6
Frequency (Hz)	60～150	90	Difference 6

Table 4 Performance Comparison				
Item		**Proposed Device**	**Predicate Device**	**Remark**
		TOPTENS-01	**Transcutaneous Electrical Nerve Stimulator (T.E.N.S)**	
For multi-program waveforms only	Symmetrical phases?	Yes	Yes	Same
	Phase Duration	100～260	208	Difference 6
Net Charge (mC per pulse)		0@500Ω，Method: Balanced waveform	0@500Ω，Method: Balanced waveform	Same
Maximum Average Current (mA)		2.22@500Ω	0.9@500Ω	Difference 7
Maximum Phase Charge, (μC)		17.16@500Ω	18.1@500Ω	Difference 7
Maximum Current Density (mA/cm², 500Ω, r.m.s)		0.14@500Ω	2.28mA/cm²@500Ω	Difference 7
Maximum Power Density		0.00015@500Ω（using smallest	0.00225@500Ω（using smallest	Difference 7

Table 4 Performance Comparison			
Item	**Proposed Device**	**Predicate Device**	**Remark**
	TOPTENS-01	**Transcutaneous Electrical Nerve Stimulator (T.E.N.S)**	
, (W/cm²) (using smallest electrode conductive surface area)	electrode 16cm²）	electrode 25cm²）	

Difference 1:

The new device TOPTENS-01 is substantial equivalence as the predicate device K152374. The differences in Power source specification（value） and Patient Leakage Current are the differences Because of the difference in structure and circuit layout, which only affect the safety performance of the device, the device is an internal power device that only uses battery power, which has lowest safety risks and has passed the safety test, so these differences will not cause any safety and effectiveness issues. Considering the same Insulation method and power source, they are substantial equivalence.

Difference 2:

The new device TOPTENS-01 is substantial equivalence as the predicate device K152374. The difference between synchronous or alternating is that only the output method of the two channal is different, The final output

waveform of the two channal is the same。They has passed the safety test, so these differences will not cause any safety and effectiveness issues. Considering the same output waveform and Output Shape, they are substantial equivalence.

Difference 3:

The new device TOPTENS-01 is substantial equivalence as the predicate device K152374.

The time range of the new device is same, and the options can be increased, in order to facilitate different use requirements. The new device has passed the safety test and the maximum time value is the same, so these differences will not cause any safety and effectiveness issues.

The new device is just an expansion of the time range and the maximum time value is the same, it can be considered that they are essentially equivalent.

Difference 4:

The new device TOPTENS-01 is substantial equivalence as the predicate device K152374. The differences in Dimensions, Weight and Housing materials construction are the differences in design requirements between different devices, which only affect the safety performance of the device, but the new device passed Safety testing, so these differences will not cause any safety and effectiveness issues. Considering the same intended use, working

principle, output mode and output waveform, they are substantial equivalence.

Difference 5:

The new device TOPTENS-01 is basically equivalent to the predicate device K152374. The difference between the maximum output voltage and maximum output current of the new device is only in the output amplitude range. This can be achieved by adjusting the appropriate output intensity to achieve the same output effect and meet the requirements of use.

Based on the same intended use, output waveform, and the new equipment has passed safety tests, these differences will not cause any new safety and effectiveness issues, they are essentially equivalent.

Difference 6:

The new device TOPTENS-01 is basically equivalent to the predicate device K152374. The difference between of Pulse Width，Frequency，Phase Duration of the new device is only in the pulse parameter . As the new device adapts to the needs of different treatment sites, a wider parameter range is required, and the parameter range of the new device can cover the predicate device， Based on the same output waveform,it can be considered to have the same validity and the predicate device.

There are no safety difference in the pulse parameters themselves. The safety risks related to these parameters are mainly as follows: Frequency is higher,

Pulse Width is wider, and Phase Duration is longer， The energy of the pulse per unit time is higher, but the pulse parameters meet the maximum current density ＜2mA/cm² And the maximum average power density ＜0.25W/cm² safety standard requirements, and passed the safety test.

Based on the same intended use, output waveform, and the new equipment has passed safety tests, these differences will not cause any new safety and effectiveness issues, they are essentially equivalent.

Difference 7:

The new device TOPTENS-01 is basically equivalent to the predicate device K152374. Maximum phase charge, maximum current density, and maximum power density are the main safety requirements. Although the some parameters of the new device is higher than that of the predicate device K152374, the value is close and at a low level. The maximum current density and the maximum power density are different because they are calculated by different electrodes, and the value is close and at a low level. But they all meet the safety standard requirements of maximum current density ＜2mA/cm² and maximum average power density ＜0.25W/cm² ,and the new device has passed the safety test. These differences will not lead to any new safety and effectiveness issues. They are essentially equivalent.

Safety comparison has been done to validate the electrical safety of the device (Table 5).

Table 5 Safety Comparison

Table 5 Safety Comparison			
Item	**Proposed Device**	**Predicate Device**	**Remark**
EMC, Electrical and Laser Safety			
Electrical safety	Comply with IEC 60601-1, IEC 60601-2-10	Comply with IEC 60601-1, IEC 60601-2-10	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Home healthcare enviroment	IEC 60601-1-11:2015	IEC 60601-1-11:2015	SE

11.Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.