October 4, 2021

Guandong Skg Intelligent Technology Co., Ltd
Fanny Yuan
Manager
No.1, 7/F, Yingfeng Business Center, No.8 Yixing Road,
Beijiao Town
Shunde District, Foshan City, Guandong Province 528303
China

Re: K200558
Trade/Device Name: Smart Neck Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: August 26, 2021
Received: September 1, 2021

Dear Fanny Yuan:

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)*
K200558

Device Name
Smart Neck Stimulator (Model: 4098 (RED))

Indications for Use *(Describe)*
The Smart Neck Stimulator is designed to be used to temporarily relieve pain associated with sore and aching muscles in the back of neck due to strain from exercise or normal household work activities.

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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510(k) Summary of K200558

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

- Company Name: GUANGDONG SKG INTELLIGENT TECHNOLOGY CO., LTD
- Establishment Registration Number: Applying
- Address: No.1, 7/F, Yingfeng Business Center, No.8 Yixing Road, Beijiao Town, Shunde District, Foshan City, Guangdong Province, China
- Postal Code: 528303
- Phone: +86 18231193066
- TEL: +86 40 0822 0888
- Contact Person (including title): Mao Hui Zhang (Certificated Engineer)
- E-mail: zhangmaohui@skg.com

2. Manufacturer

- Company Name: Guangdong Shiqi Manufacture Co., Ltd
- Address: D10-11, Lunjiao Intensive Industrial Zone, Licun Village Committee, Lunjiao Street Office, Shunde District, Foshan City, Guangdong Province, China
- Phone: +86 18231193066
- Tel: +86 40 0822 0888
- Contact Person: Mao Hui Zhang

3. Application Correspondent:

- Company: Share Info (Guangzhou) Medical Consultant Ltd.
- Contact Name: Ms. Fanny Yuan
- E-mail: medical-device@qq.com

4. Subject Device Information

Trade Name:	Smart Neck Stimulator
Common Name:	Transcutaneous Electrical Nerve Stimulator for Pain Relief
Classification name:	Stimulator, nerve, transcutaneous, over-the-counter
Review Panel:	Neurology, Physical Medicine
Product Code:	NUH
Regulation Class:	II
Regulation Number:	882.5890

5. Predicate Device Information

Sponsor	HIVOX BIOTEK INC.	Shenzhen OSTO Technology Co., Ltd.
Device Name and Model	HIVOX OTC Electrical Stimulator	Neck Care Therapy
510(k) Number	K171803	K172897
Product Code	NUH, NGX	NUH, NGX
Regulation Number	882.5890, 890.5850	882.5890, 890.5850
Regulation Class	II	II

6. Device Description

The subject device is intended to use on back of neck and it designed accord with human body cervical physiological curvature of streamlined ring design.

The device totally has 3 modes and each mode has 15 output Intensity Levels, so the device can give certain electrical pulse through the electrode pads on the skin to help users to enjoy back neck stimulation. It can also provide a constant temperature of 37℃ to 41℃ to provide a warming sensation.

The subject device can be controlled by a remote control which based on the radiofrequency technology. There are 5 buttons in the remote control, the "M" button for modes selection, "+" or "-" button for intensity selected to increase or decrease, the " " button intends to turn the heating function on and the " " button intends to turn the heating function off.

The device can be turned on when both power button on subject device has been turned on and the treatment mode can be selected by the remote control.

7. Intended Use / Indications for Use

The Smart Neck Stimulator is designed to be used to temporarily relieve pain associated with sore and aching muscles in the back of neck due to strain from exercise or normal household work activities.

8. Test Summary

Smart Neck Stimulator has been evaluated the safety and performance by lab bench testing as following:

Standards No.	Standard Title	Version	Date
IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance	2005/(R)2012 And A1:2012,	07/09/2014
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Edition 4.0 2014-02	09/17/2018
IEC 60601-2-10	Medical Electrical Equipment - Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators	Edition 2.1 2016-04	06/07/2018

Standards No.	Standard Title	Version	Date
IEC 60601-1-11	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	Edition 2.0 2015-01	06/27/2016
IEC 62133-2	Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes - Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications - Part 2: Lithium Systems	Edition 1.0 2017-02	01/14/2019
IEC 62366-1	Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices	Edition 1.0 2015-02	12/23/2016
ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity	Third Edition 2009-06-01	12/23/2016
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Third Edition 2010-08-01	07/26/2016

9. Comparison to predicate device and conclusion

The Smart Neck Stimulator has similar intended use, technological characteristics and same principle of operation as these predicate devices. Although there are several specifications different between these devices, the comparison analysis has been completed to demonstrate that the differences between these parameters would not adversely impact the safety and effectiveness of the subject device. The subject device has undergone safety and performance tests, and the results complied with the test requests. Therefore the differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
Company	GUANGDONG SKG INTELLIGENT TECHNOLOGY CO., LTD	HIVOX BIOTEK INC.	Shenzhen OSTO Technology Co., Ltd.	--
Trade Name	Smart Neck Stimulator	HIVOX OTC Electrical Stimulator	Neck Care Therapy	--
Classification Name	Stimulator, nerve, transcutaneous, over-the-counter	Stimulator, nerve, transcutaneous, over-the-counter	Stimulator, nerve, transcutaneous, over-the-counter, Stimulator, Muscle, Powered, For Muscle Conditioning	--
510(k) Number	K200558	K171803	K172897	--

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
Product Code	NUH	NUH, NGX	NUH, NGX	SE
Intended Use / Indications for Use	The Smart Neck Stimulator is designed to be used to temporarily relieve pain associated with sore and aching muscles in the back of neck due to strain from exercise or normal household work activities.	HIVOX OTC Electrical Stimulator, SEM44: TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities. EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance. HIVOX OTC Electrical Stimulator, SEM44-1: TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities.	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back of neck, back, arm, and leg, due to strain from exercise or normal household and work activities. - Neck Pad is used in back of neck. - Meridian Pad is used in shoulder, waist, back, and arm.	SE
Type of use	OTC	OTC	OTC	SE

Elements of Comparison	Subject Device		Predicate Device 1	Predicate Device 2	Remark
Power source	3.7V, 1500mAh lithium battery		4.5V (batteries, 3x1.5V AAA)	For the power adaptor: Input: 100~240Vac 50/60Hz, 0.2A; Output: 5Vdc, 1A Unit Input: 5Vdc, 1A For Battery: 3.7 Vdc, 500mAh For Remote Control: (2x1.5V AAA battery)	SE
Method of Line Current Isolation	Type BF Applied Part		Not publicly available	Type BF Applied Part	SE
Patient Leakage Current	NC	50 µA	Not publicly available	AC: 54.5µA DC: 0.5µA	SE Note 2
	SFC	100 µA	Not publicly available	AC: 120µA DC: 0.6µA	
Average current through electrodes when device is on but no pulses are being applied	<10µA		0	<0.01µA	SE Note 2
Number of Output Modes	3		TENS: 15 EMS: 35	2	SE
Heating Setting	On and off		Not publicly available	Not publicly available	SE Note 2
Heating temperature	37-41°C		Not publicly available	Not publicly available	SE Note 2
Output Intensity Level	15 steps		Not publicly available	50 steps	SE Note 2
Number of Output Channels	1		2	Not publicly available	SE Note 2
Synchronous or Alternating?	Synchronous		Synchronous	Synchronous	SE
Regulated Voltage or Current ?	Regulated voltage		Regulated voltage	Voltage Control	SE
Software / Firmware / Microprocessor Control?	Yes		Yes	Yes	SE
Automatic Overload Trip	No		Yes	No	SE
Automatic No-Load Trip	Yes		Yes	No	SE
Automatic Shut Off	Yes		Yes	Yes	SE
User Override	Yes		Yes	Yes	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
Control				
Timer Range (minutes)	15 min	5-100 min	5-30 min	SE Note 2
Weight	Main Unit: 200g	89 g (including belt clip, without batteries), 123 g (including belt clip and batteries)	Main Unit: 222g	SE Note 1
Dimensions	Main Unit: 141.4 mm x 137.9 mm x 46 mm	132 x 63 x 29.5 mm (including belt clip)	Main Unit: 187.2*169*67.3 mm	SE Note 1
Pad dimension	44.2 mm x 29.8 mm	20.25 sqcm x4 (81 sqcm)	8.9 cm *5.8 cm	SE Note 1
Housing unit	PC, ABS plastic	ABS	ABS plastic	SE
Electrode pad material	Stainless steel	Not publicly available	Stainless steel	SE
Waveform	Pulsed, symmetric, biphasic	Biphasic	Pulsed, symmetric, biphasic	SE
Shape	Rectangular, with interphase interval	Square	Rectangular, with interphase interval	SE
Maximum Output Voltage	76V±10% @500Ω 106V±10% @2KΩ 138V±10% @10KΩ	100V±10%@500Ω 180V±10% @2KΩ 250V±10% @10KΩ	44V±10% @500Ω 80V±10% @2KΩ 112V±10% @10KΩ	SE Note 2
Maximum Output Current	152mA±10% @500Ω 54mA±10% @2KΩ 13.8mA±10% @10KΩ	200mA±10% @500Ω 90mA±10% @2KΩ 25mA±10% @10KΩ	88mA±10% @500Ω 44mA±10% @2KΩ 11.2mA±10% @10KΩ	SE Note 2
Pulse Duration (μs)	Mode 1: 40μs Mode 2: 200μs Mode 3: 150μs	50-450μs	120μs	SE Note 2
Pulse frequency	1-200Hz	1-150Hz	77.3Hz	SE Note 2
Net Charge (per pulse)	0μC @ 500Ω Method: Balanced waveform	0.001 μC@500Ω	0 μC@500Ω Method: Balanced waveform	SE Note 2
Maximum Phase Charge @ 500Ω	12.16 μC	0.045 μC	12.78 μC	SE Note 2
Maximum Average Current@ 500Ω	3.9824 mA	13.5mA	0.968mA	SE Note 2
Maximum Current Density (r.m.s) @ 500Ω	0.390 mA/cm^2	0.667mA/cm^2	0.235mA/cm^2	SE Note 2
Maximum Average Power Density @ 500Ω	0.78mW/cm^2	0.00465W/cm^2	1.38mW/cm^2	SE Note 2
Operating Environment	Temperature: +10~+40°C Humidity: 45% -85%RH Atmospheric Pressure: 86 KPa – 106 KPa	Not publicly available	Temperature: 5~40°C Humidity: 15% - 90%RH Atmospheric Pressure: 700 hPa -	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
			1060 hPa	
Storage Environment	Temperature: -10~+50°C Humidity: <90%RH Atmospheric Pressure: 50 KPa – 106 KPa	Not publicly available	Temperature: -25~70°C Humidity: ≤90%RH Atmospheric Pressure: 700 hPa - 1060 hPa	SE
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	SE
Electrical Safety	IEC 60601-1 IEC 60601-2-10 IEC 60601-1-11 IEC 62133-2	IEC 60601-1 IEC 60601-2-10	IEC 60601-1 IEC 60601-1-11 IEC 60601-2-10	SE
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	SE

Comparison in Detail(s):

Note 1:

The subject has been compared with predicate devices respectively. The “Weight”, “Dimensions” and “Pad dimension” of subject device are a little different from predicate devices, but they won’t impact safety and effectiveness of subject device. Because all of them are meet the safety standards, the differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

Note 2:

The subject has been compared with predicate devices respectively. The subject device has several technological characteristics, “Number of Output Channels”, “Patient Leakage Current”, “Average current through electrodes when device is on but no pulses are being applied”, “Heating Setting”, “Heating temperature”, “Output Intensity Level”, “Timer Range (minutes)”, “Maximum Output Voltage”, “Maximum Output Current”, “Pulse Duration”, “Pulse frequency”, “Net Charge (per pulse)”, “Maximum Phase Charge @ 500Ω”, “Maximum Average Current@ 500Ω”, “Maximum Current Density (r.m.s) @ 500Ω ” and “Maximum Average Power Density @ 500Ω” are a little different from these predicate devices, but the comparison analysis has been completed to demonstrate that the differences between these parameters would not adversely impact the safety and effectiveness of the subject device. Because all of them are meet the safety standards IEC 60601-1 and IEC 60601-1-11, the differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device. Therefore, the subject device is substantially equivalent to the predicate devices K171803 and K172897.

Final Conclusion：

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that the Smart Neck Stimulator (Model: 4098 (RED)) is substantially equivalent to the predicate devices K171803 and K172897.

10. Date of the summary prepared: October 5, 2021