November 17, 2017

Smart Medical Device Co., Ltd.
% Carmelina G. Allis
Legal Representative
The Allis Law Firm
2437 Bay Area Blvd., #30
Houston, TX 77058

Re: K172451/S001
Trade/Device Name: Dr. Music 3s (Model DM-VME03S)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: September 14, 2017
Received: September 18, 2017

Dear Carmelina G. Allis and Dong-Min Lee:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William J. Heetderks -S
2017.11.17 11:47:31 -05'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Dr.MUSIC 3s (Model: DM-VME03S)

Indications for Use *(Describe)*
Dr.MUSIC 3s (Model: DM-VME03S) is intended to be used by adults for temporary relief of pain associated with sore/ aching muscles in the shoulder, waist, back, neck, upper extremities(arm) and lower extremities(leg) due to strain from exercise or normal household work activities and suitable for home 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.

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510(k) Summary of Safety and Effectiveness

SmartMedicalDevice Co., Ltd.
Dr.MUSIC 3s

1) Submitter's name, address, telephone number; Contact person

Submitter: Dong-Min Lee
Quality Management Representative
SmartMedicalDevice Co., Ltd.
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Date prepared: August 8, 2017

2) Name of the device, including the trade or proprietary name, if applicable, the common or usual name, and the classification name, if known

Device Common/Usual Name: Transcutaneous Electrical Nerve Stimulator

Device Proprietary Name: Dr.MUSIC 3s (Model: DM-VME03s)

Device Classification, Panel: Class II, Neurology

21 C.F.R. Section	Classification Name	Product Code
882.5890	Stimulator, Nerve, Transcutaneous, Over-the-Counter	NUH

3) Substantially Equivalent Devices

Dr.MUSIC 3s is substantially equivalent to the PulseRelief, cleared under K151035, and the Tanyx, cleared pursuant to K123866. Submitter is not aware of any design-related recalls regarding the predicate devices. No reference devices were used in this submission.

4) Device Description

Transcutaneous electrical nerve stimulation (TENS) is a non-invasive pain relief method. TENS treatment passes electrical pulses across the intact surface of the skin to activate the underlying nerves. The device uses a rechargeable battery to generate pulses. These pulses are applied onto the contact skin through self-adhesive reusable hydrogel electrodes.

Dr.MUSIC 3s (Model: DM-VME03S) is an over-the-counter, home-use TENS device that consists of the following components: a main unit, which consists of the control unit and the battery unit; two electrodes; an electrode case; and a mobile app. The control unit contains the

power/mode button and battery indicator, and is used to control the treatment mode and intensity level. The control unit connects to the battery unit via a Micro USB adaptor. The two re-usable adhesive hydrogel electrodes (which connect to the back of each the control unit and the battery unit using a snap button connector) deliver a low frequency pulse to the body by attaching on to the skin. The user can choose from three treatment output modes (music, tapping, or massaging) and various intensity levels.

The treatment modes and intensities can be controlled via the control unit or via a mobile app. The app allows the user to control and display the output intensity of the stimulation, change the operation mode, and display the time of use, among other features.

The mobile app can be downloaded to an iOS or Android mobile device and utilizes an icon touch-based user interface. The mobile devices must run on an operating system consisting of iOS 7.0 or later version; or Android 4.3 or later version. The mobile app and the unit communicate via Bluetooth technology.

The device components are not supplied sterile and do not require sterilization or processing prior to use.

5) Indications for Use

Dr.MUSIC 3s (Model: DM-VME03S) is intended to be used by adults for temporary relief of pain associated with sore/aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities and suitable for home use.

The device is intended for over-the-counter (OTC) use.

6) Technological Comparison to Predicate Devices

Dr.MUSIC 3s and the predicate devices are all TENS devices that employ the same basic scientific technology and operate in the same manner. All the devices deliver electrical pulses across the skin through the use of electrodes. All devices have the same intended use for the temporary relief of pain and are intended to be used in home environments by adults. Each device allows the user to place electrodes on the skin close to the area of pain. With some variations, the subject and predicate devices allow the user to choose from different treatment modes with different pulse settings and adjust the intensity of the TENS treatment.

All devices are compact, portable, and intended to be sold OTC for home use. The patient-contacting surfaces of the subject and predicate devices have been found to be biocompatible for their intended application. The subject device is manufactured and designed to the same electrical and safety standards as the predicate devices.

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510(k) Summary of Safety and Effectiveness

SmartMedicalDevice Co., Ltd.
Dr.MUSIC 3s

Comparison of Technological Characteristics with Predicate Devices

This comparison table demonstrates that the stimulation parameters of all devices are within the same range and comparable parameters. The devices include a wide variation in terms of current, voltage amplitude and waveform, but such safe and effective ranges are within the allowed variations for these product types. Maximum output current differences between Dr.MUSIC 3s and the predicate devices are due to different measurement methods, such as Peak to Peak value (Tanyx) and RMS value, but the parameters for the subject and predicate devices are in the same range of safety and effectiveness. Dr.MUSIC 3s is substantially equivalent to the predicate devices because the treatment modes and stimulation parameters (e.g., waveform, voltage, etc.) are all within the same acceptable range as those of the predicate devices.

	New Device	**Predicate Device**	**Predicate Device**
Characteristic	**SmartMedicalDevice Co.,Ltd. Dr.MUSIC 3s (Model: DM-VME03S) K_____**	**Philips Consumer Lifestyle PulseRelief K151035**	**Medecell US, Inc. Tanyx K123866**
Classification; Product Code(s)	21 C.F.R. 882.5890; NUH	21 C.F.R. 882.5890; NUH, NGX	21 C.F.R. 882.5890; NUH
Treatment Mode(s)	TENS	TENS and EMS	TENS
Intended Use/Indications for Use	For temporary relief of pain associated with sore/aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities and suitable for home use.	For the temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.	Intended to be used in adults only for temporary relief of pain associated with sore and aching muscles in the upper extremities (arms), lower extremities (legs), and lower back due to strain from exercise or normal household and work activities.
Prescription or OTC	OTC	OTC	OTC
Patient population	Adults, home use	Adults, home use	Adults, home use

510(k) Summary of Safety and Effectiveness

SmartMedicalDevice Co., Ltd.
Dr.MUSIC 3s

Characteristic		New Device SmartMedicalDevice Co.,Ltd. Dr.MUSIC 3s (Model: DM-VME03S) K_____	Predicate Device Philips Consumer Lifestyle PulseRelief K151035	Predicate Device Medecell US, Inc. Tanyx K123866
Number of output modes		3 (TENS pulse)	15 (TENS pulse) 5 (EMS pulse)	6 (TENS pulse)
Number of output channels		1	1	1
Waveform		Biphasic	Biphasic	Monophasic
Shape		Rectangular	Rectangular	Rectangular
Maximum output	**Current**	@500Ω: 10.4mA± 10%	@500-1000Ω:60mA	@500Ω: 95.2mA
	Voltage	38Vpk	60V	@500Ω: 47.6Vpp
Software/Firmware/Micro-processor control?		Yes	Yes	Yes
Patient Override Control		Yes (Power on/off in device and mobile app, intensity)	Yes (Power on/off in device and mobile app)	Yes (Power on/off, intensity)
Timer range		5~30 min (Preset app.: 20min)	1 to 59 minutes and continuous	None set, but labeling recommends a minimum of 20-30 minutes per treatment session
Stimulation parameters	**Frequency range**	1~100Hz	1~100Hz	55Hz
	Pulse Width (duration)	50-150μs	60-350μs	80μs

510(k) Summary of Safety and Effectiveness

SmartMedicalDevice Co., Ltd.
Dr.MUSIC 3s

	New Device	Predicate Device	Predicate Device
Characteristic	**SmartMedicalDevice Co.,Ltd. Dr.MUSIC 3s (Model: DM-VME03S) K_____**	**Philips Consumer Lifestyle PulseRelief K151035**	**Medecell US, Inc. Tanyx K123866**
Electrode	Hydrogel, Attaches to skin	Hydrogel, Attaches to skin	Gel pads, Attaches to skin
Power	Power Input: DC 5V,1A Internally powered Equipment: 3.7V(Li-Poly Type), 400mAh (rechargeable)	Adapter type; 100~240V, 50/60Hz AC/DC adapter: 5V-300mA Battery type: Li-Ion 3.7V, 500mAh (rechargeable)	3-volt lithium cell CR2025 (non-rechargeable; product to be disposed when battery depletes)
Weight	54.5g	62g	30g
Dimension	56(W)mm×56(D)mm×12.8(H)mm, Length of cable : 200mm	53.5×53.5×11.5 mm	153x51x8.2mm (Electrode cable: No)
Electrode dimensions	4.5cm x 4.5cm (2 pcs)	50mm x 50 mm (2 pcs)	-
App on mobile device	Yes (iOS and Android platforms)	Yes (iOS and Android platforms)	-
Housing Materials	PolyCarbonate	PC ABS	Acrylonitrile Butadiene Styrene (ABS) and Polypropylene (PP)

7) Determination of Substantial Equivalence - Performance Data

Dr.MUSIC 3s is substantially equivalent to the predicate devices with respect to intended use, principles of operation, and technological characteristics. As described below, the electrical safety, electromagnetic compatibility, usability, software and biocompatibility assessments found that the proposed device conforms to the same applicable standards and specifications as the predicate devices, which demonstrate that Dr.MUSIC 3s is substantially equivalent to the predicate devices.

Non-clinical performance data

Non-clinical tests relied on this premarket notification submission for a determination of substantial equivalence include testing showing compliance with the following standards:

Electrical Safety, EMC, and RF Wireless Capabilities

Electrical safety, electromagnetic compatibility, and RF wireless capabilities were evaluated per international standards and the device complies with the following standards:

- IEC 60601-1: Medical Electrical Equipment
- IEC 6001-2-10: Medical Electrical Equipment -- Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators.
- 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
- IEC 60601-1-6: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366: Medical devices - Application of usability engineering to medical devices
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Usability Testing

Usability testing was conducted according to IEC 62366. The usability engineering process was conducted to assess and mitigate risks associated with the correct use of the device as well as user errors. The test results demonstrate that the product has been found to be reasonably safe and effective for the intended users and intended use environments through usability engineering process.

Risk Management Assessment

The risk of use of the product to its intended users and environment was assessed according to ISO 14971. All identified hazards were reduced to acceptable levels.

Biocompatibility

Biocompatibility testing was conducted in accordance with ISO 10993-5 and ISO 10993-10. The patient-contacting surfaces of the device (electrodes) were evaluated for cytotoxicity, skin irritation and skin sensitization. Test results demonstrate that the patient-contacting surfaces of Dr.MUSIC 3s, like the patient-contacting surfaces of the predicate devices, meet biocompatibility standards.

Software Evaluation and Cybersecurity Management

Software validation and verification activities, and cybersecurity management activities, were conducted pursuant to IEC 62304 and were found acceptable. Documentation was provided per FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

Clinical tests and animal studies - not conducted

Dr.MUSIC 3s does not introduce new indications for use, modes, features, or technologies relative to the predicate devices that would require evaluation through clinical or animal testing. The clinical safety and effectiveness of TENS devices with technological characteristics equivalent and similar to those of the proposed device are well accepted, and clinical or animal testing is not necessary to make that assessment.

8) Conclusion

In conclusion, the tests conducted, as well as all verification and validation activities, demonstrate that the design specifications and technological characteristics of the proposed device meet applicable requirements and standards for a determination that the proposed device is as safe and as effective as the predicate devices. There are some differences in technological characteristics between the predicate and proposed devices, but those differences only indicate that the predicate devices may have secondary or additional functionalities to those of Dr.MUSIC 3s. The testing and validation activities conducted demonstrate that any differences in technological characteristics do not raise new or different questions of safety or effectiveness as compared to the predicate devices. Therefore, the proposed device is substantially equivalent to the predicate devices.