DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 1, 2017

Sunstar Suisse S.A.
% Calley Herzog
Senior Consultant
Biologics Consulting Group
400 N. Washington St., Suite 100
Alexandria, Virginia 22314

Re: K163448
Trade/Device Name: GrindCare System
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback Device
Regulatory Class: Class II
Product Code: HCC, KZM, NUW
Dated: August 3, 2017
Received: August 4, 2017

Dear Calley Herzog:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Andrew I. Steen -S

for Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K163448

Device Name
GrindCare System

Indications for Use *(Describe)*

The GrindCare System is indicated to aid in the evaluation and management of sleep bruxism by reducing the temporalis muscle EMG activity during sleep.

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 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the GrindCare System is provided below.

Device Common Name:	**Biofeedback Device**
Device Trade Name:	**GrindCare System**
Applicant:	Sunstar Suisse S.A. Route de Pallatex 11, 1163 Etoy Switzerland +41-21-821-0500
Prepared by:	Calley Herzog Senior Consultant Biologics Consulting Group, Inc. cherzog@biologicsconsulting.com Phone: 720-883-3633 Fax: 703-548-7457
Date Prepared:	**August 31, 2017**
Classification Regulation:	882.5050 – Biofeedback device, Class II
Panel / Product Code:	Neurology / HCC
Secondary Product Codes:	KZM - Diagnostic Electromyograph NUW - Powered Muscle Stimulator, Dental
Predicate Device:	GrindCare, K092675

Indication for Use:

The GrindCare System is indicated to aid in the evaluation and management of sleep bruxism by reducing the temporalis muscle EMG activity during sleep.

Device Description:

The GrindCare System is a portable electromyographic (EMG), electrical stimulation, and biofeedback device. It consists of a Sensor that is adhered to the skin over the temporalis muscle by means of an adhesive, disposable, single-use GelPad. The System also includes a Docking Station, USB Cable, and Power Adaptor. The Sensor and Docking Station record and store EMG activity data, which is transferred from the Docking Station to the GrindCare Mobile App, which allows the user to review grinding and stimulation data and enter diary notes. The Sensor uses EMG to sense contraction of the temporalis muscle that is associated with bruxing events. In response to the EMG-measured contraction, it delivers mild electrical stimulation that is intended to relax the muscle and inhibit the bruxing event. Bruxism is the occurrence of

(typically sleep) grinding and clenching of the jaw and is one of the most common sleep disorders.

The components of the GrindCare System:

- Sensor: A self-contained and battery powered component, to be placed on the skin of the patient. It records EMG activity and reacts with electrical stimulation when muscle activity is detected.
- Docking Station: A USB-powered device, where the Sensor is inserted when not in use for charging and to transfer data. Both charging and data transfer is performed wirelessly.
- USB Cable: A USB cable with a micro-USB connector in one end and a standard USB connector at the other end used for power (no data transfer is possible).
- Power Adapter
- GelPad: GrindCare is to be used with an adhesive, single-use GelPad. One pack of 28 GelPads is provided with the device and additional GelPads can be purchased separately. The GrindCare device is not intended to be used with any other gel pads.
- GrindCare App: An iOS and Android mobile app that allows the user to review grinding and stimulation data and enter diary notes.

Substantial Equivalence Discussion:

The predicate device is a previous version of the GrindCare System and was cleared in K092675. The predicate device is based on the same principle of operation as the subject device, but uses a modified detection algorithm. The table below provides a comparison of the technological features of the subject device to the predicate device.

	Proposed Device	**Predicate Device**
510(k) Number	TBD	K092675
Applicant	Sunstar	Medotech A/S
Device Name	GrindCare System	GRINDCARE
Classification Regulation	882.5050	882.5050
Product Code **Subsequent Product Codes**	HCC: Biofeedback Device NUW: Powered Muscle Stimulator, Dental KZM: Muscle Monitoring Device, Dental	HCC: Biofeedback Device NUW: Powered Muscle Stimulator, Dental KZM: Muscle Monitoring Device, Dental
Number of Output Channels	1	1
Number of Output Modes	1	1
Waveform	Biphasic symmetrical	Biphasic symmetrical

	Proposed Device	Predicate Device
Shape	Rectangular	Rectangular
Placement	On the skin at the temple, over the Temporalis Anterior muscle.	On the skin at the temple, over the Temporalis Anterior muscle.
Regulated Current or Regulated Voltage?	Regulated Current	Regulated Current
Maximum Output Voltage	40 V	40 V
Maximum Output Current	7 mA	7 mA
Pulse Width	500 µs	500 µs
Frequency	230 pulses/sec	230 pulses/sec
Net Charge	0 (charge balanced)	0 (charge balanced)
Maximum Phase Charge	1.75µC	1.75µC
Maximum Current Density	35mA/cm^2	35mA/cm^2
Maximum Power Density	0.022 W/cm^2	0.022 W/cm^2
Electrode	Conductive gel w/adhesive galvanic tripolar electrode	Conductive gel w/adhesive galvanic tripolar electrode
Input Impedance	4.4MOhms	4.4MOhms
Common Mode Rejection Ratio	90dB	90dB
Power Source / Charging	70mAh LiPo IEC 62133 compliant Lithium-ion rechargeable battery in the Sensor Inductive (wireless) link for charging the Sensor battery.	340mAh LiPo Lithium-ion rechargeable battery in the Stimulator and GrindDock Gold spring contacts for charging the Stimulator when docked in the GrindDock.
Average Battery Charge Time	3.5 hours	3.5 hours
Communication	Infrared link for transferring data from Sensor to Docking Station. Bluetooth communication for transferring data from Docking Station to GrindCare App.	Zigbee type radio link for communication between Stimulator and GrindDock
Data Storage	Sensor stores only a single session of data. Docking Station stores up to 5 years of data.	Stimulator stores up to 30 sessions of data. No data stored on the GrindDock.

	Proposed Device	Predicate Device
PCB Size	35x19mm	45x30mm
Microprocessor	Docking Station: MSP430-F5333 processor Sensor: MSP430-F5338 processor	GrindDock: MSP430-F2618 processor Stimulator: MSP430-F2618 processor
Viewing the Data	Bluetooth type radio link for communication between Docking Station and GrindCare App on an iOS or Android device. There is no display on the device. Mobile App is used to view the data.	Data transferred by USB to a PC. LCD display on the GrindDock.
Grind Threshold	Automatically calculated continuously based on background noise.	Determined by user input before each use.

Comparison of Indications:

Predicate device indication statement (K092675):

> The GRINDCARE device is indicated to aid in the evaluation and management of nocturnal bruxism by reducing the temporalis muscle EMG activity during sleep.

Subject device indication statement:

> The GrindCare System is indicated to aid in the evaluation and management of sleep bruxism by reducing the temporalis muscle EMG activity during sleep.

As shown above, the indication statement of the subject device is equivalent to that of the predicate device. The term “nocturnal bruxism” has been replaced with “sleep bruxism”, to reflect the generally accepted terminology used in the scientific community to describe the behavior, as this type of bruxism is linked to the awake/sleep state and not to the time of day/night. The change is a clarification of the indication statement and does not represent a change to the intended use.

Discussion of Technological Differences:

Power Source / Charging - In the predicate device both the GrindDock and the Stimulator were battery powered. In the subject device the Sensor battery is charged wirelessly. The lithium-ion battery complies with the FDA-recognized standard IEC 62133. Power to the Docking Station comes from a USB adapter or a USB port. Performance testing demonstrated the functionality of the wireless charging.

Communication - The predicate device used a Zigbee type radio link for communication between Stimulator and GrindDock. The subject device uses an infrared link for transferring data from Sensor to Docking Station and Bluetooth communication for transferring data from the Docking Station to the GrindCare App. Performance testing demonstrated the functionality of

communication between the Sensor and the Docking Station and between the Sensor and the GrindCare App.

Data Storage - In the predicate device, the Stimulator stored up to 30 nights of data. In the subject device, the Sensor stores one night of data, but every time it is inserted into the Charger, the data is transferred. The Charger can store data from up to 5 years of typical use. Performance testing demonstrated the functionality of the data storage and transfer.

PCB Size - All input and output circuitry relating to patient contact is unchanged and specifications are the same. Only the circuitry that generates the compliance voltage for the stimulation circuit has been redesigned, to reduce size and improve efficiency. Performance testing demonstrated the functionality of the PCB.

Microprocessor - The microprocessor chosen for the subject device is similar to the processor in the predicate device. There are no differences that have any impact on functionality or performance requirements for the subject device compared to the predicate device. Performance testing demonstrated the functionality of the microprocessor.

Viewing the Data - In the predicate device, the data was viewed on the GrindDock device, on the LCD display or was uploaded to a PC to be viewed in a dedicated program, the GrindCare Manager. In the subject device, the data is viewed on a portable device, based on either the Android operating system or the iOS operating system (iPhones, iPads). Performance testing demonstrated the functionality of the GrindCare App.

Grind Threshold - Like the predicate device, the subject device detects grinds by comparing the amplitude of the signal generated by the user's muscle activity to a baseline, or background noise level. The subject device calculates the threshold differently than the predicate device. This difference in setting the threshold for a grinding event does not change the intended use of the device as a biofeedback system for reducing muscle activity during sleep. For both devices, a grind is defined as measured muscle activity that is quantifiably above background noise. Once a grind is detected, the subject device provides the identical stimulation signal as was provided by the predicate device. Performance testing demonstrated equivalent performance of the grind detection algorithm to the predicate device.

Shelf Life - The 510(k) for the predicate device did not indicate a shelf life, the GelPads are now labeled with a shelf life of 24 months. Performance testing demonstrated that the device meets specifications after 24-months.

Performance Data Provided to Establish Substantial Equivalence:

Type	**Description of Testing or Standard Referenced**
Verification Testing	Hardware, Algorithm and System Level Testing was completed to verify that the device meets design and performance specifications and is equivalent to the predicate device.
Safety	IEC 60601-1: 2005 + CORR1:2006 + CORR.2:2007 + AM1:2012 Medical electrical equipment -- Part 1: General Requirements for basic safety and essential performance

Type	Description of Testing or Standard Referenced
	IEC 60601-2-40: 1998 Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment
	IEC 60601-1-6: 2010 (Third Edition) + A1:2013 Medical electrical equipment Part 1-6 General requirements for safety - Collateral Standard: Usability
	IEC 60601-1-11: 2010 (First edition) Medical Electrical Equipment – Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical System Used in Home Healthcare Environment
EMC	IEC 60601-1-2 Edition 3: 2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.
Battery Certification	IEC 62133 Edition 2.0: 2012-12, 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
Wireless Coexistence	Testing to demonstrate wireless coexistence with other FR transmitters common in the home environment.
Biocompatibility of Gelpad	ISO 10993-5:2009 biological evaluation of medical devices - part 5: tests for in vitro cytotoxicity.
	ISO 10993-10: 2010 biological evaluation of medical devices - part 10: tests for irritation and skin sensitization
Shelf Life	Shelf life testing was performed that demonstrates the device continues to meet performance specifications for the 24-month shelf life of the gelpads.
Usability Testing	Subjects were observed while completing device and app critical tasks. Use error information (including an evaluation of labeling comprehension) was analyzed. The study demonstrated that users and prescribers were able to perform the tasks associated with use of the GrindCare device with the GrindCare App.
Clinical Data	The clinical study demonstrated that the modified detection algorithm decreased the number of EMG events per hour by 32.45% over baseline. Like the predicate device, the subject device demonstrated a statistically significant reduction on the number of EMG events per hour on a representative patient population.

Substantial Equivalence:

The predicate device is a previous version of the GrindCare System and was cleared in K092675. The subject device has the same intended use as the predicate device and delivers the identical stimulation signal. The technical differences between the subject device and the predicate device are supported by performance testing to demonstrate that the differences do no raise new questions of safety or effectiveness. Therefore, the subject device can be found substantially equivalent to the predicate device.