November 22, 2019

TimeWaver Production GmbH
% Douglas Herrington
Principal Consultant
Herrington Consulting LLC
2885 Sanford Ave, SW #43083
Grandville, Michigan 49418

Re: K191075
Trade/Device Name: Healy
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH, NYN
Dated: October 30, 2019
Received: November 12, 2019

Dear Douglas Herrington:

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,

Pamela D. Scott -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191075

Device Name
Healy

Indications for Use *(Describe)*
The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arms and legs due to strain from exercise or normal household work activities and for the 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary: K191075

General Information

Date: May 26, 2019

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Regulatory Information

Device Name: Healy
510(K) Number: K191075
Classification: Class II
Panel: Neurological Therapeutic Devices
Product Code: NUH, NYN
Regulation Number: 21 CFR 882.5890, Transcutaneous electrical nerve stimulator for pain relief

Indication for Use Statement

The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arms and legs due to strain from exercise or normal household work activities. And for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

Environments of Use: Clinics, hospital and home environments.

Patient Population: All adults 18 years and older.

510(k) Summary: K191075

Substantial Equivalence Summary

Table 1: Substantial Equivalence Comparison Table	Microcurrent	Microcurrent	Comparison
510(k) Number	K191075	K172079	
Regulation	21 CFR§882.5890	21 CFR§882.5890	No Difference
Product Code	NUH, NYN	NUH	Similar, Healy adds product code NYN, however Omron's IFU states arthritis pain treatment but the 510k approval is for only NUH.
Device Name	Healy	Avail, Model PM601	
Manufacturer	TimeWaver Production GmbH	Omron Healthcare Inc	
Usage	Over the Counter	Over the Counter	No Difference
Intended Use	The Healy is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, legs, shoulders or feet due to strain from exercise or normal household work activities. For the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.	The Avail is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, legs, shoulders or feet due to strain from exercise or normal household work activities. When used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis, use the Tap, Shoulder, Arm or Leg mode of stimulation.	No Difference
Environment of Use	Environments of Use: Clinics, hospital and home environments.	Environments of Use: Clinics, hospital and home environments.	No Difference
Patient Population	Patient Population: All adults 18 years and older.	Patient Population: All adults 18 years and older.	No Difference
Contraindications/ Warnings/ Precautions	Contraindications: Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or	Contraindications: Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or	No Difference

	electronic device. Such use could cause electric shock, burns, electrical interference, or death.	electronic device. Such use could cause electric shock, burns, electrical interference, or death.	
Single Use	Patient-contacting Pads are for single patient use	Patient-contacting Pads are for single patient use	No Difference
Sterility	External contacting device, nonsterile	External contacting device, nonsterile	No Difference
Over-the-Counter: (OTC)	Yes	Yes	No Difference
Power Source: Voltage	Rechargeable Lithium Ion Battery	Rechargeable Lithium Ion Battery	No Difference
Method of Line Current Isolation	N/A (internal power source)	N/A (internal power source)	No Difference
Patient Leakage Current			
-normal Condition, uA	0	<10	Similar with Healy having somewhat lower leakage current
- Fault Condition, uA	0	<50	Similar with Healy having somewhat lower leakage current
Average DC Current Through electrodes when device is on but no pulses are being applied (uA)	<1	0.0	No Difference
Number of Output Modes	1 Microcurrent mode	1 Microcurrent mode 9 TENS modes	No Difference as Healy only compares to the Microcurrent mode.
Number of Output Channels	1	1	No Difference
Synchronous or Alternating	N/A	N/A	No Difference
Method of Channel Isolation	none	none	No Difference
Regulated Current or Regulated Voltage	both (Software control)	current	Similar with Healy providing both current and voltage regulation.
Software/Firmware/Microprocessor Control?	Microprocessor	Microprocessor	No Difference
Automatic Overload Trip	Yes	no	Similar with Healy adding an additional safety feature.
Automatic No Load contact Trip	Yes	yes	No Difference
Automatic Shut Off	Yes	yes	No Difference
User Override Control?	Yes, power On/Off button on the device and in the App software	Yes, power On/Off button on the device and in the App software	No Difference
Indicator Display			

On/Off Status	Yes, on the App and LED indicator on Main unit	Yes, on the App and LED indicator on Main unit	No Difference
Low Battery?	Yes on app and LED indicator on device	YES, ON APP	No Difference
Voltage/Current	YES, ON APP	YES, ON APP	No Difference
Timer Range (minutes)	1min - 180min	5-60 minutes and 30-180 minutes for Microcurrent	Similar with Heal having additional timing control of 1- 30 minutes
Compliance With Voluntary standards?	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11	No Difference
Compliance with 21 CFR 898	Yes	N/A no patient cable	Different with Healy complying with 21 CFR 898.
Weight	device 34g electrode 2g	Device: Approx. 42 g Pad-L: Approx. 21 g Pad-M: Approx. 17.5g Charger: Approx. 100g	Healy is lighter than the SE as the pads are smaller and no charger is provided.
Dimensions (W x H x D). mm	device : 55 x 55 x 7 pads: 32mm round x 5mm height	Device: Approx. 60 × 72 × 15.5 Charger: Approx. 158 x 90 x 20.5 Pad-L: Approx. 219 × 83.5 × 9.3 Pad-M: Approx. 180 × 79.5 × 9.3	Healy pads are smaller than the predicate because they do not deliver TENS voltages/currents, and no charger is provided. See the technical discussion.
Operating Conditions	5°C - 40°C 15-93%RH 700-1060hpa	10 to 40 °C 30 to 80 %RH 700 to 1060 hPa (noncondensing)	Similar with Healy having slight higher relative humidity
Charging Conditions	5-40°C 15-93% RH.	5 to 35 °C 30 to 80 %RH	Similar with Healy having slight higher relative humidity
Storage Conditions	5-40°C 15-93% RH.	0 to 40 °C 30 to 80 % RH	Similar with Healy having slight higher relative humidity and slightly lower temperature
Transporting Conditions	-20 to 60 °C 15-93% RH	-20 to 60 °C 10 to 90 % RH	Similar with Healy having slight higher relative humidity and slightly lower temperature
Electrode Style	Reusable	Reusable	No Difference
Patient Contact Accessory?	Yes	Yes	No Difference

Table 2: Output Comparison Microcurrent mode			
510(k) Number	K191075	K172079	Comparison
Product Code	NUH, NYN	NUH	
Device Name	Healy	Avail, Model PM601	
Manufacturer	TimeWaver Production GmbH	Omron Healthcare Inc	
Waveform	Biphasic	Biphasic	No Difference
Shape	Rectangular	Rectangular	No Difference
Max Output Voltage (V)			
500 Ohms	0.030	0.025	Similar with Healy having slightly higher output current.
2k Ohms	0.100	0.100	No Difference
10k Ohms	0.500	0.500	No Difference
Maximum Output Current (mA)			
500Ohm	0.050	0.050	No Difference
2kOhm	0.050	0.050	No Difference
10kOhm	0.050	0.050	No Difference
Pulse Duration, Sec	2.50	2.50	No Difference
Frequency, Hz	0.20	0.20	No Difference
Net Charge (uC per charge) @ 500 ohms	0	0	No Difference
Maximum Phase Charge (uC), 500 Ohms	125.0	125.0	No Difference
Maximum Average Current, mA	0.025	0.025	No Difference
Maximum Current Density, mA/cm^2			
500 Ohms	0.0010	0.0008	Similar with Healy having slightly higher current density.
2k Ohms	0.001	---	Unknown as the predicate does not give a value
10k Ohms	0.001	---	Unknown as the predicate does not give a value

510(k) Summary: TimeWaver Production GmbH

Maximum Average Power [mW/cm²]			
500Ohm	0.00002500	0.00001398	Similar with Healy having slightly higher maximum average power.
2kOhm	0.0000100	----	The predicate does not mention the value
10kOhm	0.0000500	----	The predicate does not mention the value
Regulated Current or Voltage?	Current	Current	No Difference

510(k) Summary: K191075

Discussion of Healy and Avail similarities and differences

PREDICATE DEVICE(S) [807.92(a)(3)]
The Healy device is substantially equivalent to the primary predicate device, the Omron Avail Microcurrent mode (K172079) with regard to product labeling, intended use, anatomical sites, patient population, performance testing, technological and safety characteristics.

DEVICE DESCRIPTION [807.92(a)(4)]
The Healy device is a single channel wearable electrotherapy device that is designed to alleviate temporary and chronic muscle and joint pain on multiple body locations. It delivers microcurrent therapy through the simple and convenient use of the dedicated iOS or Android App, or on product controls. Reusable, self-adhesive and contouring electrodes allow for discreet and convenient placement on multiple pain locations on the body.

The system contains one unit, which is rechargeable and is attached to the electrode via cables. The electrode can then be applied to intact skin at the desired location for therapy and pain relief. Control of the Healy system is completed through the available App or on product controls. The Healy will be packaged with an Instruction Manual and quick start guide that provides details on setting up the device for use, installing of the App, setting and controlling therapy modes, and troubleshooting. The system includes the unit, adhesive gel electrodes, USB charging cable, electrode connection cable, and storage case.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES, [807.92(a)(6)]
In regard to technological characteristics, the Healy device is similar to the predicate with only minor technological differences. Like the predicate Avail device, the Healy device is paired and controlled by a dedicated smartphone App and on product controls with treatment duration and intensity being controlled by the App or product controls. However, both proposed and predicate devices can be turned off by pressing the on/off button on the main unit or the App. The Healy device and the Avail both offer one microcurrent mode. The Healy and Avail both use biphasic rectangular waveform. Both products use microcurrent low-level electrical stimulation and share the same regulation number (21 CFR 882.5890) the same product codes of NUH and NYN. The Avail instruction booklet (pg 26 of the attached Avail IB) states, "*Any of the modes can be used on body parts or pains described in this instruction manual of the device"*, which includes the microcurrent mode.

The microcurrent mode is considered a very low current TENS (rectangular biphasic waveform) delivered at a low frequency. A comparison of the Healy operating characteristics to the primary predicate is included in the 510k summary.

In general, the Healy output parameters fall within the range of output parameters for Avail. For example, the maximum current density (mA/cm2) range for Healy @ 500 ohms is 0.0010, while the Avail is 0.0008. This range is also well below the IEC60601-2-10:2012 (Clause 201.4.2) limit of less than 2mA/cm2. The maximum average power density (W/cm2) @500 ohms is 0.00002500 for Healy, whereas the Avail maximum average power density @500 ohms is 0.00001398.

The Healy and Avail differ in how the electrode pads are configured. The Avail has pads that do not use lead wires, where the Healy does use lead wires. Additionally, the Healy pads are 32mm round where the Avail is 180 x 80mm because Healy only delivers microcurrent stimulation whereas the Avail also delivers TENS voltages and currents. The Healy electrodes and cables comply with 21 CFR 898 so they do not raise new questions of safety or effectiveness.

The proposed device, predicate device and reference devices are all intended for use as transcutaneous electrical nerve stimulation in adult populations for use in clinic, hospital or home settings. TimeWaver has completed comprehensive design verification testing, electrical safety and electromagnetic compatibility testing, software verification and validation to ensure that the Healy device performs as intended. The Healy also passed all testing requirements for electrical safety and EMC, and the device electrode has been previously cleared by FDA. The minor differences in labeling and technological characteristics between the proposed device and the predicate device have been evaluated and determined to not raise different questions of safety or effectiveness. As such, the proposed Healy is substantially equivalent to the predicate device. A comparison table summarizing the specifications and features of the proposed Healy device and the predicate device is included in the 510k summary.

Performance Data [807.92(b)]
All necessary non-clinical testing was conducted on the Healy device to confirm that the device performs as intended.

Nonclinical Testing Summary:
The nonclinical, bench testing included performance verification to confirm acceptable performance of device features and functions. Other nonclinical safety testing included:

- Electrical safety and electromagnetic compatibility testing
- Software verification and validation

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the Healy meet the established specifications.

Performance Data: Electromagnetic Compatibility and Electrical Safety

The Healy device has been thoroughly tested against applicable EN and IEC standards by a third p arty and found to be in compliance with the applicable sections. It was functionally tested and found to be in compliance with the specification.

The applicable electrical and safety standards met are:

IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
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
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 60601-2-10: Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

EN 301 489-1 &17: Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment

TCRL 2015-2: Bluetooth RF Compliance

Software Validation

The Healy device software was validated following FDA's Guidance for the Content of Premarket Submissions for Software contained in Medical Devices.

The applicable software validation standards met are:
EN 62304_ Medical device software – Software life cycle processes
EN ISO 13485: 2012_ Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971: 2012_ Medical devices – Application of risk management to medical devices
EN 62304: 2006_ Medical device software – Software life cycle processes
EN 62366: 2008_ Medical devices – Application of usability engineering to medical devices

Biocompatibility Data

Biocompatibility testing is not required because the only patient contact surface is through the electrode which was previously cleared by FDA.

Non-Clinical Testing - Other
In addition to electrical safety testing and software validation, human factors analysis and testing was also conducted and no user issues were identified.

Conclusion

Based upon the intended use and technical information provided in this pre-market notification, the Healy device has been shown to be safe and effective and substantially equivalent to the currently marketed predicate device.