October 19, 2021

MyoWorx Inc.
% Darren Reeves
President
DP Distribution & Consulting, LLC.
12240 Hunting Horn Lane
Rockville, Virginia 23146

Re: K192746
Trade/Device Name: MyoWorx TM20
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: July 15, 2021
Received: July 15, 2021

Dear Darren Reeves:

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
CDR Jitendra Virani, MS
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)*
K192746

Device Name
MyoWorx TM20

Indications for Use *(Describe)*
Muscle relaxation and increased local blood circulation.

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
Traditional 510(k)

In accordance with 210 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the MyoWorx TM20 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:	MyoWorx Inc. 77 Westmount Road Suite 201 Guelph, Ontario, N1H5J1
Contact Person/Prepared by:	Darren Reeves President DP Distribution & Consulting, LLC (804) 307-7706 dreeves@dpdconline.com 7305 Hancock Village Drive Suite 109 Chesterfield, Virginia 23832
Date:	10/13/2021
Subject Device:	**Trade Name:** MyoWorx TM20 **Common Name:** Powered Muscle Stimulator **Classification Name:** Powered Muscle Stimulator (21 CFR 878.5850, Product Code IPF)
Predicate Device:	Mettler Electronics Corp., Sys*Stim® 294 (ME294) (K984114)

Purpose and Device Description:
The TM20 is a device used for muscle relaxation. It sends biphasic pulses to targeted distressed muscles, and by delivering a specified sequence of timed and abrupt electrical frequency pulses, the device can be used to decrease the tension of the muscle fibers and leads to greater blood flow.

The user operates the device by means of a keypad overlay. The overlay allows for the user to adjust the treatment length, adjust intensity of each stimulation output, adjust maximum power of stimulation, and start, pause, and stop

treatment. The values being set and current stage of treatment is displayed to the user by means of an LCD display, alpha numeric displays, and LEDs.

Future revisions of the product are intended to be controlled by means of a Laptop or Tablet which will rest on the surface of the enclosure and connect to the device by means of a Slave USB cable. This capability will be implemented in hardware but not firmware.

The TM20 device consists of the following:

1. User Interface Overlay
2. External Power Supply for TM20
3. A main board for controlling and monitoring the generated output
4. 10 Individual output channels, and a stimulation circuit for each channel
5. Communication and stimulation cables
6. A custom bent metal enclosure

The TM20 device is designed, assembled, and tested to medical device standards of a Class 2 device which meets all safety and regulatory requirements for Health Canada and the FDA. The device is designed to operate from 10-35 degrees Celsius.

Intended Use and Indication for Use:
Muscle relaxation and increased local blood circulation.

Comparison of Predicate Device:
The MyoWorx TM20 is substantially equivalent in intended use, design, technology/principles of operation, materials, and performance to the Sys*Stem ® 294 (ME294) (K984114). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Side by Side Device Comparison Table:
Predicate Device, Sys*Stim® 294 (ME294) and Proposed Device, MyoWorx TM20

Elements of Comparison	**Subject Device**	**Predicate Device (K984114)**	**Similarity**
Device Name	MyoWorx TM20	Sys*Stim® 294 (ME294)	N/A
510 (k) Number	Applying	K984114	N/A
Product Code	IPF	IPF, LIH and GZJ	Substantially equivalent
Regulation Number	882.5890	882.5890	Same

Intended Use	Muscle relaxation and increased local blood circulation.	1. Symptomatic relief of chronic pain, acute post traumatic pain or acute post-surgical pain (interferential, Premodulated and Microcurrent waveforms). 2. Temporary relaxation of muscle spasm, (all waveforms except Microcurrent). 3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles, (all waveforms except Microcurrent). 4. Increase of blood flow in the treatment area (all waveforms except Microcurrent). 5. Prevention or retardation of disuse atrophy in post-injury type conditions, (all waveforms except Microcurrent). 6. Muscle re-education, (all waveforms except Microcurrent). 7. Maintaining or increasing range of motion, (all waveforms except Microcurrent).	Substantially equivalent
Power Source	UL Listed Medical Grade Power supply cable between 100-240VAC, 50/60Hz	Detachable U.L. Listed, hospital-grade line cord (ME 7293) between 90-240 VAC, 50-60Hz	Substantially equivalent

Method of Line Current Isolation	External 60601 power supply plus output transformers rated at 4,000VAC	Yes	Same
Patient Leakage current -Normal condition -Single fault condition	< 100 uA < 100 uA	<100 uA <100 uA	Same
Number of Output Modes	1	6	Different
Number of Output Channels	10	4	Different
Automatic Overload Trip	Yes	Yes	Same
Automatic No-load Trip	N/A	Yes	N/A
Automatic Shut Off	No	Yes	Different
Patient Override Control	No	No	Same
Compliance with CFR 898	No	No	Same
Housing Materials and Construction	Aluminum. Two machined, bent, and welded parts. One machined part. Fastened by screws.	Aluminum. Stamped in a flat pattern, embossed, folded into a box shape and seams welded and ground flush.	Substantially equivalent
For inferential modes only: Beat Frequency (Hz)	N/A	1-250Hz +/- 2Hz or 10% whichever is greater	N/A
For multiphasic waveforms only: Symmetrical phases	Biphasic pulses are symmetric	Biphasic pulses are symmetric	Same
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV Contact ±15 kV Air	±6 KV Contact ±8 kV Air	Substantially equivalent
Electrical fast transient/bust IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines ±1 kV for input/output lines	Same

Surge IEC 61000-4-5	±0.5kV, ±1 kV Line to Line ±0.5kV, ±1 kV, ±2 kV Line to Ground	±1 kV differential mode ±2 kV common mode	Substantially equivalent
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% $\mathbf{U_T}$ (100% dip in $\mathbf{U_T}$) for 0.5 cycle 0% $\mathbf{U_T}$ (100% dip in $\mathbf{U_T}$) for 1 cycles 70% $\mathbf{U_T}$ (30% dip in $\mathbf{U_T}$) for 30 cycles 0% $\mathbf{U_T}$ (100% dip in $\mathbf{U_T}$) for 5 seconds	<5% $\mathbf{U_T}$ (>95% dip in $\mathbf{U_T}$) for 0.5 cycle 40% $\mathbf{U_T}$ (60% dip in $\mathbf{U_T}$) for 5 cycles 70% $\mathbf{U_T}$ (30% dip in $\mathbf{U_T}$) for 25 cycles <5% $\mathbf{U_T}$ (>95% dip in $\mathbf{U_T}$) for 5 seconds	Substantially equivalent
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	3 A/m	Substantially equivalent
Conducted RF IEC 61000-4-6	3 Vrms, 150 kHz-80 MHz 6 Vrms ISM/Amateur radio bands inside 150 kHz-80MHz	3 Vrms	Substantially equivalent
Radiated RF IEC 61000-4-3	3 V/m, 80 MHz-2.7GHz RF communication equipment inside 80 MHz-6GHz	3 V/m	Substantially equivalent
Input	100-240V 1.4A, 50/60Hz	90-240VAC, 50-60Hz, 2.3 Amp Nom.	Substantially equivalent
Operating Temperature	10℃ to 35℃	+50℉ to +104℉	Substantially equivalent
Humidity	Operating, Relative	Operating, 30% to	Substantially

	Humidity 30% to 75% Non-Condensing Storage, Relative Humidity 10% to 90% Non-Condensing	75% Relative Humidity at 104℉ Nonoperating, 5 to 95% Relative Humidity, non-condensing	equivalent
Storage Temperature	-10 ℃ to 60℃	-40℉ to 167℉	Substantially equivalent
Timer Accuracy	±25 parts per million (ppm)	±30 seconds	Different
Timer Range	30, 45, 60 and 90 minutes	Maximum Time 60 minutes	Different
Console Weight	5.2 pounds (without accessories)	9.4 pounds	Substantially equivalent
Dimensions	3.45” (thickest point) and 1.26” (thinnest point) x 14.000”x8.690” (HxWxD)-excluding feet	5” (H) x 14.5” (W) x 10” (D)	Substantially equivalent
Waveform	Biphasic or Monophasic, Rectangle	Interferential, Premodulated, Medium Frequency, Symmetrical Biphasic, High Volt, and Microcurrent, Square	Substantially equivalent
Maximum Output Voltage (+/- 10%)	0V-75V +/-5% (peak), with 1kOhm loads	99 volts peak, 1Kohm load (Symmetrical Biphasic)	Different
Maximum Output Current	0.120A, with 500Ohm load	7.2 mA	Different
Frequency Range	1-120Hz	1-120Hz	Same
Pulse Width Range	200µs	50-300µs	Substantially equivalent
Method of Line Current Isolation	External 60601 power supply plus output transformers rated at 4,000VAC	Yes	Substantially equivalent
Synchronous or Alternating	Synchronous	Unknown	Unknown
Regulated Current	Voltage	Unknown	Unknown

or Regulated Voltage			
Software/Firmware Microprocessor control	Firmware microprocessor control	Microprocessor control	Same
Indicator Display On/Off Status	Yes	Yes	Same
Indicator Display Low Battery	N/A	N/A	Same
Indicator Display Voltage/Current Level	Yes	Yes	Same
Net Charge	24ucoulombs per pulse	Unknown	Probably equivalent
Maximum Current Density	0.0032A/sqcm	0.0036A/sqcm	Substantially equivalent
Maximum Power Density	0.09W/sqcm	Unknown	Probably equivalent
On Time	19.5 seconds	1-240 seconds	Different
Off Time	0.5 seconds	1-240 seconds	Different

Substantial Equivalence Conclusion:
After performing non-clinical performance studies, the data shows that the MyoWorx TM20 is substantially equivalent to the predicate in its sole function as a powered muscle stimulator for temporary relief of muscle spasms. The subject device has fewer functions than the predicate and the differences between it and the predicate device do not raise new issues of safety or effectiveness. Regarding any differences, the following paragraphs provide additional explanations:

Number of output modes: The predicate device has six different output modes versus one output mode in the MyoWorx TM20. The single output mode in the subject device is the same as the "Biphasic" output mode in the predicate device. Not having the same number of output modes as the predicate does not raise new issues of safety or effectiveness and simplifies the function and operation of the subject device.

Number of output channels: The predicate device has four channels and the MyoWorx TM20 device has 10 channels. This difference allows the TM20 device to apply the intended effect to more muscles at one time as compared with

predicate device. As demonstrated through clinical validation, this difference does not impact upon safety or effectiveness.

Automatic shut-off: The MyoWorx TM20 does not automatically shut-off but rather goes into a sleep mode with all outputs turned off other than an indicator LED light.

Timer Accuracy: The timer in the MyoWorx TM20 has greater accuracy than the predicate.

Timer Range: The minimum time of 30 minutes and maximum time of 90 minutes for the TM20 versus a selectable range of up to 60 minutes for the predicate device does not affect safety or effectiveness as current delivery in the MyoWorx TM20 is applied for a maximal allowable duration, which is greater than 10 times less the allowable duration of the predicate.

Maximum Output Voltage: The predicate device has a maximum output voltage of 99 volts (output mode same as subject device) and the MyoWorx TM20 has a maximum voltage of 75 volts. The TM20 device is substantially as safe as the predicate due to the lesser maximum voltage output and substantially as effective as the voltage level is well within the physiological range to produce the intended effect of muscle relaxation and increased local blood circulation.

Maximum Output Current: The predicate device has a lower maximum output current than the subject device, however safety or effectiveness is not affected as current delivery in the MyoWorx TM20 is applied for a maximal allowable duration, which is greater than 10 times less the allowable duration of the predicate.

On-Time: Selectable for the predicate and preset for the subject device, controlling safe delivery of the stimulus.

Off-Time: Selectable for the predicate and preset for the subject device.

None of the above-identified differences have any adverse effect on the safety or effectiveness of the subject device when compared with the predicate.