June 17, 2022

Thought Technology Ltd.
Suresh Sugirtharaja
Acting Regulatory Affairs Manager
5250 Ferrier, Suite 812
Montreal, Quebec H4P 1L3
Canada

Re: K213197
Trade/Device Name: MyOnyx System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ
Dated: June 6, 2022
Received: June 7, 2022

Dear Suresh Sugirtharaja:

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,

CDR Jitendra Virani
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)*
K213197

Device Name

MyOnyx System

Indications for Use *(Describe)*

The MyOnyx System is intended for use as a powered muscle stimulation device for relaxation of muscle spasms and muscle re-education, prevention or retardation of disuse atrophy, maintaining or increasing range of motion, increasing local blood circulation, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

The MyOnyx System may also be used for transcutaneous electrical nerve stimulation (TENS) and microcurrent electrical stimulation (MET) for the symptomatic relief of acute and chronic intractable pain.

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 K213197

June 15, 2022

Device Trade Name:	**MyOnyx System**
Regulation Number:	21 CFR §890.5850
Regulation Name:	Powered muscle stimulator
Product Code:	IPF
Regulation Number:	21 CFR §882.5890
Regulation Name:	Transcutaneous electrical nerve stimulator for pain relief
Product Code:	GZJ
Regulatory Class:	Class II
Manufacturer:	Thought Technology Ltd.
Establishment Reg. No:	9680487
Address:	5250 Ferrier, Suite 812 Montreal, Quebec H4P 1L3 CANADA Tel: +1 (514) 489-8251 Fax: +1 (514) 489-8255
Regulatory Contact:	Suresh Sugirtharaja, Acting Regulatory Affairs Manager E-mail: suresh@thoughttechnology.com

This 510(k) Summary has been prepared in accordance with 21 CFR §807.92. It summarizes device safety and effectiveness information to provide an understanding of the basis for a determination of substantial equivalence.

Predicate Device:	Combo Stimulator MT9000 (K171978, Product Codes: IPF, GZJ)
Reference Device:	MyOnyx System (K201014, Product codes: KPI, HCC)

Indications for Use / Intended Use

The MyOnyx System is intended for use as a powered muscle stimulation device for relaxation of muscle spasms and muscle re-education, prevention or retardation of disuse atrophy, maintaining or increasing range of motion, increasing local blood circulation, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

The MyOnyx System may also be used for transcutaneous electrical nerve stimulation (TENS) and microcurrent electrical stimulation (MET) for the symptomatic relief of acute and chronic intractable pain.

Caution: US Federal law restricts this device to sale by or on the order of a licensed health-care practitioner.

Device Description

The MyOnyx System is a multi-functional, palm-sized, 4-channel device with embedded firmware and accessories designed for use in physical therapy and rehabilitation under medical supervision. The system that is subject to this 510(k) provides pre-loaded programs and allows users to define programs for electrical muscle stimulation (EMS), transcutaneous electrical nerve stimulation (TENS), and microcurrent stimulation (MET).

Biofeedback and incontinence-related indications for use of the device have been cleared under K201014.

The device can send a gentle, clinician-adjustable electrical current to underlying nerves and muscles via off-the-shelf surface electrodes cleared by the FDA for this purpose. EMG signals may also be acquired using off-the-shelf, FDA-cleared surface EMG electrodes.

The device may be used for muscle and nerve stimulation in one of the following operating modes:

- As a standalone device (autonomous mode); or
- With the MyOnyx Mobile App running on an off-the-shelf tablet (remote control mode).

The device is operated via a graphical interface on an LCD screen and a capacitive touch pad with haptic and audio feedback. The connection to a tablet is wireless, via Bluetooth®. Visual, audio and voice feedback and prompts are provided to facilitate device operation.

Stimulation data are not recorded. When used in remote control mode, the device can record on the tablet root-mean-square (RMS) EMG signal data at 20 samples/s.

The device is powered by an internal rechargeable Li-ion polymer battery or via a medical grade power supply / battery charger. The internal battery offers up to 8 hours of autonomous device operation.

Performance Data

The MyOnyx System was evaluated using a risk management process in accordance with ISO 14971. Verification and validation testing of system specifications, basic safety and essential performance was conducted in conformance with current recognized consensus standards for this device type considering regulatory guidance for powered muscle stimulators, wireless technology, and cybersecurity:

Test	**Test Method / Standard (FDA Recognition No.)**	**Acceptance Criteria**
Electrical safety	IEC 60601-1 / ES60601-1:2012 (FR# 19-4)	Conformity to applicable basic safety and performance requirements
EMC	IEC 60601-1-2:2014, 4th Ed. (FR# 19-8)	Conformity of device emissions and device immunity to EM disturbances for use in a professional healthcare facility
Basic safety and essential performance of nerve and muscle stimulators	IEC 60601-2-10:2012+A1:2016 (FR# 17-16)	Conformity of electrical stimulation programs to applicable requirements

Test	Test Method / Standard (FDA Recognition No.)	Acceptance Criteria
Basic safety and essential performance of electromyographs and electrical stimulators	IEC 60601-2-40:2016	Conformity of electrical stimulation programs to applicable requirements for accuracy of controls and protection against hazardous stimulation output
Verification of hardware device controls and interfaces	Each device circuit block was verified against hardware design specifications under normal use and single fault conditions, as appropriate.	Test results must meet or exceed hardware design specifications
Usability	IEC 60601-1-6:2010+A1:2013 (FR# 5-89) in conjunction with IEC 62366-1:2015 (FR# 5-114)	Conformity of the Usability Engineering Process and related outputs. Acceptance of the modified device by representative end-users operating the device as per accompanying instructions for use.
Software life-cycle processes	IEC 62304:2006+A1:2015 (FR# 13-79)	Firmware development in conformity with requirements for Class B software ('Moderate Level of Concern')
Stimulation firmware unit testing	The Class B (per IEC 62304) stimulation firmware functions and safety features were tested with inputs that verify the effectiveness of error handling and risk control measures	The device responds with expected outputs meeting software design specifications when supplied with predefined test inputs
Firmware and system-level functional verification testing	Device functions were tested in autonomous mode and in remote control mode with the MyOnyx Mobile App	The device responds with expected outputs meeting software design specifications under anticipated use conditions and inputs

Clinical testing was not required to demonstrate substantial equivalence for this device type. The clinical literature supports the safety and clinical utility of the stimulation modes for the stated indications for use.

Substantial Equivalence Comparison & Conclusion

The appended table shows the side-by-side comparison of the subject device to the predicate device for key device characteristics and safety and performance standards used to demonstrate substantial equivalence.

The assessment of device differences shows that the MyOnyx System does not raise new or different questions of safety and effectiveness as compared to the predicate device for the stated indications for use. The results from verification and validation activities (non-clinical testing) support a finding of substantial equivalence as they demonstrate that the subject device fulfills its design and risk management requirements by meeting safety and performance standards that are equivalent to those met by the identified predicate and reference devices.

Side-by-side comparison with the predicate device

Device characteristics	Subject device: MyOnyx System	Predicate device: Combo Stimulator MT9000 (K171978)	Comparison to predicate / Brief SE justification
Product Code	IPF, GZJ	IPF, GZJ	Same
Indications for Use	The MyOnyx System is intended for use as a powered muscle stimulation device for relaxation of muscle spasms and muscle re-education, prevention or retardation of disuse atrophy, maintaining or increasing range of motion, increasing local blood circulation and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis. The MyOnyx System may also be used for transcutaneous electrical nerve stimulation (TENS) and microcurrent electrical stimulation (MET) for the symptomatic relief of acute and chronic intractable pain.	For TENS/IF/MIC mode: 1. Symptomatic relief of chronic intractable pain 2. Post traumatic pain 3. Post surgical pain For EMS mode: 1. Relaxation of muscle spasm 2. Increase of local blood flow circulation 3. Prevention or retardation of disuse atrophy 4. Muscle re-education 5. Maintaining or increasing range of motion 6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.	Same
Operating Modes	• Standalone (autonomous mode via 3.5in LCD and capacitive touch pad with haptic feedback device controls); • With the MyOnyx App on a tablet (remote control mode via Bluetooth®)	• Standalone (autonomous mode via custom-segment LCD and control buttons)	Different The optional remote control mode does not raise different questions of safety & effectiveness. The safety, performance, and usability of the subject device have been verified and validated for both operating modes using the same methods as those used for the reference MyOnyx device (K201014).
Input / Output Channels	4 channels (2 channels for either electrical stimulation or EMG input for ETS; and 2 channels for electrical stimulation only)	2 output channels for electrical stimulation	Different The two additional channels do not raise different questions of safety & effectiveness. Both devices meet basic safety and essential performance standards.
Multi-channel Stimulation	Yes (Synchronous or alternating)	Yes (Synchronous, alternating, or delayed)	Same

Device characteristics	**Subject device: MyOnyx System**	**Predicate device: Combo Stimulator MT9000 (K171978)**	**Comparison to predicate / Brief SE justification**
Electrical Muscle Stimulation (EMS)			
Delivery Method	Repeated cycles of work and rest phases delivered on one or two channels with one of seven pre-loaded programs or user defined programs	Repeated cycles of work and rest phases delivered on two channels with user defined programs	Different Delivering stimulation using preloaded programs that may be adjusted by the clinician does not change the intended use or indications for use of the device and does not raise different questions of safety & effectiveness. Both devices allow for similar adjustable stimulation parameters (stim time, rest time, ramp-up/down time, session time, pulse width, pulse frequency, and pulse amplitude/current). Built-in safety features keep the output current, max charge per pulse, and power density below safety thresholds. Both devices meet basic safety and essential performance standards considering worst case stimulation parameters. The subject device output was verified using the same methods as those used for the reference MyOnyx device (K201014).
Waveform	Symmetrical, rectangular, bipolar, biphasic	Symmetrical, square wave, biphasic	
Frequency	5 – 80 Hz, 5 Hz/step	1 – 150 Hz, 1 Hz/step	
Pulse Width	150 – 400 µs, 5 µs/step	50 – 300 µs, 10 µs/step	
Ramp-up/down	0 – 9.9 s, 100 ms/step	0 – 6 s, 1 s/step	
Pulse Amplitude (Output Current)	0 – 100 mA, 1 mA/step (Regulated)	0 – 100 mA, 1 mA/step (Regulated)	
Max Current	100 mA ± 20% @ 500 Ω 39 mA ± 20% @ 2 kΩ	96 mA ± 20% @ 500 Ω 105 mA ± 20% @ 1 kΩ	
Max Voltage	50 Vpp ± 5% @ 500 Ω 78 Vpp ± 5% @ 2 kΩ	48 Vpp ± 20% @ 500 Ω	
Safety Features	No stimulation below 200 Ω and above 4 kΩ load	Over-current trip; over-load trip	
Max Charge per Pulse @500 Ω	80 µC	Not stated	
Max Power Density @500 Ω	0.027 W/cm^2 (25 cm^2 electrode conductive surface area)	Not stated (min 16 cm^2 electrode conductive surface area)	
Surface EMG specifications			
EMG Signal Processing	16-bit Analog to Digital Converter, Bipolar, 2048 samples/s; 20 Hz – 500 Hz (Band-Pass Filter)	No EMG input	Different The optional surface EMG input does not change the intended use or indications for use of the device and
CMMR	> 100 dB		

Device characteristics	Subject device: MyOnyx System	Predicate device: Combo Stimulator MT9000 (K171978)	Comparison to predicate / Brief SE justification
Input Impedance	≥ 10 MΩ		does not raise different questions of safety & effectiveness. The subject device meets current basic safety and essential performance standards. The off-the-shelf surface electrodes and verification methods are the same as those used for the reference MyOnyx device (K201014).
Digital Output	20 samples/s RMS signal		
EMG Accuracy	±3%		
Surface EMG Electrodes	Uni-Gel™ Single Electrodes (Single Use), Thought Technology Ltd, #T3425		
Transcutaneous Electrical Nerve Stimulation (TENS)			
Delivery Method	Continuous (no rest phase); Burst mode (2 bursts/s); Frequency modulation; Frequency and amplitude modulation (delivered via 2 pre-loaded programs for acute or chronic pain; or via user-defined programs)	Continuous (no rest phase); Burst mode (0.5-5 bursts/s); Pulse rate modulation; Pulse width modulation (delivered via user-defined programs)	Different Non-significant differences in stimulation parameters do not raise different questions of safety & effectiveness. Both devices allow for similar adjustable stimulation parameters (session time, pulse width, pulse frequency, and pulse amplitude/current). Built-in safety features keep the output current, max charge per pulse, and power density below safety thresholds. Both devices meet basic safety and essential performance standards considering worst case stimulation parameters. The subject device output was verified using the same methods as those used for the reference MyOnyx device (K201014).
Waveform	Symmetrical, rectangular, bipolar, biphasic	Symmetrical, square, biphasic	
Frequency	2 – 150 Hz, 1 Hz/step up to 20Hz, 5 Hz/step above 20 Hz	1 – 150 Hz, 1 Hz/step	
Pulse Width	50 – 250 µs, 5 µs/step	50 – 300 µs, 10 µs/step	
Pulse Amplitude (Output Current)	0 – 100 mA, 1 mA/step (Regulated)	0 – 100 mA, 1 mA/step (Regulated)	
Max Current	100 mA ± 20% @ 500 Ω 39 mA ± 20% @ 2 kΩ No stimulation above 4 kΩ load impedance	96 mA ± 20% @ 500 Ω 105 mA ± 20% @ 1 kΩ	
Max Voltage	50 Vpp ± 5% @ 500 Ω 78 Vpp ± 5% @ 2 kΩ	48 Vpp ± 20% @ 500 Ω	
Safety Features	No stimulation below 200 Ω and above 4 kΩ load	Over-current trip; no load trip; over-load trip	

Device characteristics	Subject device: MyOnyx System	Predicate device: Combo Stimulator MT9000 (K171978)	Comparison to predicate / Brief SE justification
Max Charge per Pulse @500 Ω	50 µC (accounting for bipolar pulse)	Not stated	
Max Power Density @500 Ω	0.031 W/cm^2 (25 cm^2 electrode conductive surface area)	Not stated (min 16 cm^2 electrode conductive surface area)	
Microcurrent Electrical Nerve Stimulation (MET)			
Delivery Method	Continuous (no rest phase) (delivered via pre-loaded program)	Continuous (no rest phase); Pulse rate modulation; Pulse width modulation (delivered via user-defined programs)	Different The subject device does not offer adjustable waveform parameters for microcurrent stimulation but the default parameters are within the range of available options with the predicate device. Non-significant differences in stimulation parameters do not raise different questions of safety & effectiveness. Both devices meet basic safety and essential performance standards considering worst case stimulation parameters.
Waveform	Symmetrical, rectangular, bipolar, monophasic, polarity revesal	Symmetrical, square, monophasic	
Frequency	0.5 Hz (fixed)	1 – 150 Hz, 1 Hz/step	
Pulse Width	500 ms (fixed)	2 – 200 ms, 1 ms/step	
Pulse Amplitude (Output Current)	600 µA (Regulated)	0 – 700 µA, 10 µA/step (Regulated)	
Max Current	600 µA ± 20% @1 kΩ	760 µA ± 20% @500 Ω	
Max Voltage	0.30 Vpp ± 5% @ 500 Ω	0.36 Vpp ± 20% @ 500 Ω	
Stimulation Electrodes (All Stimulation Modalities)			
Cutaneous Stim. Electrodes	5 cm x 5 cm PALS® Neurostimulation Electrodes (K132422)	4 cm x 4 cm electrodes (minimum size, FDA cleared)	Similar off-the-shelf cutaneous electrodes
Physical and Electronic Component Characteristics			
Device Size	155 mm x 83 mm x 21 mm	114 mm x 65 mm x 23 mm	Different Differences in physical and electronic component characteristics do not raise different questions of safety & effectiveness.
Weight	272 g	127 g	
Enclosure Materials	Polycarbonate and ABS blend;	ABS	

Device characteristics	**Subject device: MyOnyx System**	**Predicate device: Combo Stimulator MT9000 (K171978)**	**Comparison to predicate / Brief SE justification**
	Plexiglass tinted front panel, aluminum ring for structural support		The subject device is designed consistent with FDA cybersecurity and wireless technology guidance for medical devices, and in conformity with current basic safety and essential performance standards for medical electrical equipment.
Data Display	3.5 in diagonal, 72 mm x 54 mm, 24-bit color, backlit LCD (320 x 240 pixels)	2in diagonal, custom-segment LCD	
Data Storage	8GB Embedded Multi-Media Card (eMMC)	No	
Communication	v4.1 Bluetooth®	No	
Electrical Safety Specifications			
Power Source	Internal Battery (not user replaceable): Rechargeable (3200mAh) Li-ion Polymer battery certified to IEC 62133 – up to 8 hours of autonomous device operation; or External 15W, 5V Medical Grade (Class II Double Insulated) Power Supply / Battery Charger	Internal Battery (user replaceable): 9V Alkaline; or External medical grade power adapter (800 mA)	Different The differences in power source characteristics and options do not raise different questions of safety & effectiveness. Both devices meet basic safety and essential performance standards for medical electrical equipment.
Safety & Performance Standards	IEC 60601-1:2005+A1:2012 IEC 60601-2-10:2012+A1:2016 IEC 60601-2-40:2016 IEC 60601-1-2:2014 IEC 60601-1-6:2013/IEC 62366-1:2015 IEC 62304:2006+A1:2015 IEC 62133:2012 ISO 15223-1:2016	IEC 60601-1 IEC 60601-2-10 IEC 60601-1-2 IEC 62304	Different The differences in certain standards do not raise different questions of safety & effectiveness. The subject device meets current basic safety and essential performance standards for medical electrical equipment as applicable for its technological characteristics and the intended use environment.