September 20, 2018

Katalyst Inc.
Bjoern Woltermann
Chief Executive Officer, Katalyst Inc
316 Occidental Ave.
South Suite B300
Seattle, Washington 98104

Re: K181199
Trade/Device Name: Katalyst Mark 1 Muscle Stimulation System Model 2
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: June 22, 2018
Received: June 26, 2018

Dear Bjoern Woltermann:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Vivek J. Pinto -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181199

Device Name
Katalyst Mark 1 Muscle Stimulation System Model 2

Indications for Use *(Describe)*
The Katalyst Mark 1 is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.

It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the training programs or operational parameters are designed to target injured or ailing muscles and its use on such muscles is contraindicated.

The Katalyst Mark 1 is Rx only.

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

This summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter

Katalyst Inc.
316 Occidental Avenue S.
Suite B300
Seattle, WA 98104

Contact: Bjoern Woltermann - Chief Executive Officer, Katalyst Inc.
Tel: (206) 488-3939
Email: bjoern@katalyst-fitness.com

Previously Cleared Devices: K171035 Katalyst Mark 1 Muscle Stimulation System

2. Date Prepared

September 20, 2018

3. Device Name and Classification Information:

Trade/Proprietary Name: Katalyst Mark 1 Muscle Stimulation System Model 2
Model Number: 2
Common Name: Powered Muscle Stimulator for Muscle Conditioning
Classification Name: Powered Muscle Stimulator
Classification: 21 CFR 890.5850, Class II
Product Code: NGX
Panel: 89, Physical Medicine

4. Predicate Devices

Primary Predicate: Compex® Sport Plus (K083140)
Secondary Predicate: E-Fit EF-1280 (K133225)

5. Device Description

The Katalyst Mark 1 Muscle Stimulation System Model 2, commonly referred to as Katalyst Mark 1, consists of the following three main components:

Katalyst Suit	Worn by the client, the Katalyst Suit consists of a base layer textile (client contacting), a cable harness, and an outer layer for the cable harness to snap into corresponding electrode pads for major muscle groups. When connected to the Impulse Pack, it provides localized EMS impulses to major muscle groups at controlled intensities.
Impulse Pack	A powered muscle stimulation device specifically designed to mate with the Katalyst Suit through a single port connector. It delivers EMS impulses through a battery powered regulated booster. The Impulse Pack receives commands over Bluetooth from the Katalyst Training Station which is controlled by the operator.
Katalyst Training Station	The Katalyst Training Station is based on an MSI computer running Windows 10. It is paired with a touch screen and rotary encoders which are used to configure and run a training via the Katalyst Application. The adjustment of independent intensities for each muscle group are done using 10 smaller knobs to adjust channel intensities and 1 larger knob to control the overall master intensity.

Table 014- 1 Katalyst Mark 1 Component Overview

Accessories included: Cable Harnesses for connecting Impulse packs and Katalyst Suits, Impulse Pack Charging Adaptors and Katalyst Training Station Power Cords.

6. Indications for Use:

The Katalyst Mark 1 is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.

It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the training programs or operational parameters are designed to target injured or ailing muscles and its use on such muscles is contraindicated.

The Katalyst Mark 1 is Rx only.

7. Basic Device Characteristics - Comparison with Predicate Devices

Characteristic	New Device (Katalyst Mark 1 Muscle Stimulation System)	Primary Predicate Compex Sport Plus (K083140)	Secondary Predicate: E-Fit EF-1280 (K133225)	Similar/ Different
Device Name, Model	Katalyst Mark 1 Muscle Stimulation System, Model 2	Compex Sport Plus (currently marketed as Compex Sport Elite)	E-Fit EF-1280	K083140 - Different K133225 - Different

Manufacturer	Katalyst Inc.	DJO LLC	FIT-PRO KFT LTD.	K083140 -Different K133225 - Different
Indications for Use	The Katalyst Mark 1 is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the training programs or operational parameters are designed to target injured or ailing muscles and its use on such muscles is contraindicated. The Katalyst Mark 1 is Rx only.	The Compex® Sport Plus is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The Compex® Sport Plus is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the Compex® Sport Plus training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. The Compex® Sport Plus electrical impulses allow the triggering of action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones are transmitted to the muscle fibers via the motor endplate where they	E-fit EF-1280 is a machine with electronic muscle stimulation based on EMS technology. Regarding its use, the device is specifically designed as an addition to other sports and for training muscles. It must be used for only healthy muscles and clients, not for rehabilitation purposes. The E-Fit EF-1280 intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The E-Fit EF-1280 is not intended to be used in conjunction with therapy or treatment of medical	K083140 - Similar K133225 - Similar

		generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles. The various types of muscle work that the Compex® Sport Plus can impose on the stimulated muscles are able to improve or facilitate muscle performance. The Compex® Sport Plus may therefore be considered a technique of muscle training	diseases or medical conditions of any kind. None of the E-Fit EF-1280 training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. The E-Fit EF-1280 electrical impulses allow the triggering of action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction,	

			duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles. The various types of muscle work that the E-Fit EF-1280 can impose on the stimulated muscles are able to improve or facilitate muscle performance. The E-Fit EF-1280 may therefore be considered a technique of muscle training.	
Connection of device to electrodes	The Katalyst Impulse Pack is connected to the electrodes via a cable harness. The connection to the Impulse Pack is via a standard MDR connector, and snapping onto the electrodes using standard SNAP connectors integrated in the electrodes themselves.	With 6-pole cables including female custom SNAP plugged on the custom Compex female SNAP assembled in the electrode. Entire electronic circuit for four (4) Stimulation Channels and User Interface is combined into same casing, connected to the electrodes with 6-pole cables.	The EF-1280 unit is connected to the electrodes via a cable electrode harness which is connected to the EMS device with a physical connection. The connection to the EMS device is via a plastic 12pin waterproof ip68 Connector and the connection to the electrodes	K083140 - Similar K133225 - Similar

			is via SNAP connectors directly onto the outer vest and leg straps.	
Power Source(s)	Li-Po Battery 3.8V, 7.79Wh (2050mAh) IEC 62133: 2012 (2nd Edition)	Rechargeable Ni-Mh Battery 4.6V (4 cells AA=R6)	Lead Acid Battery 12V, 3400mAH	K083140 -Different K133225 - Different Difference does not adversely affect the safety and effectiveness of the device
Charging System	AC/DC wall plug in, distributed directly to the device. 18.0[v], 1.33[A]	AC/DC 9[v] 0.4[A] Distributed directly to the device	AC/DC wall plug in, distributed directly to the device.	K083140 - Different K133225 - Different Difference does not adversely affect the safety and effectiveness of the device
Waveform	Bipolar Square	Bipolar Square	Bipolar Square	K083140 – Similar K133225 - Similar
Channels	10	4	12	K083140 - Different K133225 - Similar
Operation Modes	1	9	5+5	K083140 - Different K133225 - Different

				See section 1.10 Differences below for justification of differences
Charging Isolation	Yes	Yes	Yes	K083140 - Similar K133225 - Similar
Rechargeable Integrated Battery	Yes	Yes	Yes	K083140 - Similar K133225 - Similar
Display / Control Interface	Yes; LCD Display on Katalyst Training Station	Yes, Integrated (LCD)	LCD 2x40 character LCD display with LED backlight. The rotary encoder allows for a quick setup and ease of use	K083140 - Different K133225 - Similar
Per Channel Control	Yes. Using rotary encoder knobs for each channel.	Yes, Using integrated buttons.	Yes. Using rotary encoder knobs for each channel.	K083140 - Similar K133225 - Similar
Electrode Placement	Placed into outer layer, appropriately positioned over corresponding muscle group positions. Cannot be modified/altered.	Not defined. Placement of electrodes is dictated by the operator.	Placed into outer layer, appropriately positioned over corresponding muscle group positions. Cannot be modified/altered.	K083140 - Different K133225 - Similar
Electrode Leads	21 CFR 898 compliant.	21 CFR 898 compliant.	21 CFR 898 compliant.	K083140 - Similar K133225 - Similar
Electrode Interface	4mm Standard SNAP Connector.	4mm Standard SNAP Connector.	4mm Standard SNAP Connector.	K083140 - Similar

				K133225 - Similar
Electrodes	2 per channel; Max 20.	2 per channel; Max 8.	2 per channel; Max 24.	K083140 - Similar K133225 - Similar
Transthoracic stimulation	Yes	No	Yes	K083140 - Different K133225 - Similar electrode placement and safety mitigations as K133225
Wireless Communication with Control Interface	Yes. Utilizing Bluetooth Smart (BT LE 4.0).	No	No	K083140 - Different K133225 - Different See section 1.10 Differences below for justification of differences
Mobile / Form Factor	Portable with difficulty, no mobile device, its intended use requires a Katalyst certified operator.	Yes (pocket device with travel case)	Portable with difficulty, no mobile device, its intended use requires the qualified and trained operator.	K083140 – Different K133225 - Similar
Channel Control Interface	Using rotary encoder knobs for each channel and master rotary encoder for all channels.	Physical Buttons and Display on unit.	Using rotary encoder knobs for each channel and master rotary	K083140 – Different K133225 - Similar

			encoder for all channels.	
Instant Shutoff	Physical Button	Physical Button	Physical Button	K083140 - Similar K133225 - Similar
Microprocessor Controlled?	Yes	Yes	Yes	K083140 - Similar K133225 - Similar
Automatic overload trip?	Yes	Yes	Yes	K083140 - Similar K133225 - Similar
Automatic No-Load Trip?	No	Yes	Yes	K083140 - Different K133225 – Different See section 1.10 Differences below for justification of differences
Automatic Shutoff?	On/Off Switch	On/Off Switch	On/Off Switch	K083140 - Similar K133225 - Similar
Patient Override Control?	No	Yes	Yes	K083140 - Different K133225 - Different See section 1.10 Differences below for justification of differences
Interface Indicators	On/Off - Yes (on Impulse Pack via LED	On/Off - yes Low Battery - yes	On/Off - yes	K083140 - Similar

	and the Katalyst application). Low Battery - Yes (on Impulse Pack). Voltage/Current Level - Yes (in the Katalyst application). Charging - yes (on Impulse Pack). Duration of training- yes (in the Katalyst application)	Voltage/Current Level - yes Charging - yes Duration of training training- yes.	Low Battery - yes Voltage/Current Level - yes Charging - yes Duration of training training- yes.	K133225 - Similar
Duration in minutes	20	55	30 minutes	K083140 - Similar K133225 - Similar
Rx Only or OTC	Rx Only	OTC	Rx Only	K083140 - Different K133225 - Similar

Table 014- 2 Device Characteristic Comparisons

8. Output Specification - Comparison with Predicate Devices

Characteristic	New Device (Katalyst Mark 1 Muscle Stimulation System)	Primary Predicate: Compex Sport Plus (K083140)	Secondary Predicate: E-Fit EF-1280 (K133225)	Similar/ Different
Waveform	Symmetrical Biphasic	Symmetrical Biphasic	Symmetrical Biphasic	K083140 - Similar K133225 - Similar
Shape	Rectangular	Rectangular	Rectangular	K083140 - Similar

				K133225 - Similar
Maximum Output Voltage (+/- 10%)	60 V @ 500 Ω 96 V @ 2 kΩ 114.2 V @ 10 kΩ	60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ	36 V @ 500 Ω	K083140 - Similar K133225 - Different
Maximum Output Current (+/- 10%)	120 mA @ 500 Ω 48 mA @ 2 kΩ 11 mA @ 10 kΩ	120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ	72 mA @ 500 Ω	K083140 - Similar K133225 - Different
Positive Pulse Width	175µs symmetrical	200 µs to 400 µs	100µs to 500µs	K083140 - Different K133225 - Similar
Negative Pulse Width	175µs symmetrical	200 µs to 400 µs	100µs to 500µs	K083140 - Different K133225 - Similar
Frequency	85Hz	1 to 120Hz	5 to 120Hz	K083140 - Similar K133225 - Different
For interferential modes only:	No	No	No	K083140 - Similar K133225 - Similar
-Beat Frequency	No	No	No	K083140 - Similar K133225 - Similar
For multiphasic waveforms only:	Yes	Yes	Yes	K083140 - Similar K133225 - Similar
- Symmetrical phases?	Yes	Yes	Yes	K083140 - Similar K133225 - Similar
- Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	175µs Symmetrical	200-400µs Symmetrical	100 - 500µs Symmetrical	K083140 - Different K133225 - Similar

Net Charge	0.5 [µC] @ 500Ω Excitation pulse fully compensated	0 [µC] @ 500Ω Excitation pulse fully compensated	0 [µC] @ 500Ω Excitation pulse fully compensated	K083140 - Similar K133225 - Similar
Maximum Phase Charge	21µC @ 500 Ω	48µC @ 500Ω	36µC @ 500 Ω	K083140 - Similar K133225 - Similar
Maximum Current (RMS) Density	0.788mA/cm^2 @500Ω	1.49mA/cm2 @ 500Ω	0.85mA/cm2 @ 500Ω	K083140 - Different K133225 - Similar
Maximum Power Density	8.16mW/cm^2 @ 500 Ω	27.6mW/cm2 @500Ω	6.3mW/cm2 @ 500 Ω	K083140 - Different K133225 - Similar
Burst Mode (i.e., pulse trains) a. Pulses per burst b. Bursts per second c. Burst duration (seconds) d. Duty Cycle [Line (b) x Line (c)]	N/A	Unknown	Unknown	K083140 -Unknown K133225 - Unknown
ON Time	4 second intervals	Not Adjustable	0.1 to 60 seconds, 0.1 second intervals (adjustable within range)	K083140 - Different K133225 - Similar
OFF Time	4 second intervals	Not Adjustable	0.1 to 60 seconds, 0.1 second intervals (adjustable within range)	K083140 - Different K133225 - Similar
Treatment Training Time	20 minutes	Not Adjustable	1-30 minutes, 1-minute intervals (adjustable within range)	K083140 - Different K133225 - Similar
Ramp up time per impulse	300 ms	Not Adjustable	0 ms - 5000 ms, 100ms	K083140 - Different

			intervals (adjustable within range)	K133225 - Similar

Table 014- 3 Output Specification Comparisons

9. Differences

When comparing the core design, output specifications, operating behavior, intended use and general modes of operation it can conclude there is little difference between the Compex Sport Plus, EF-1280, and the Katalyst Mark 1 Muscle Stimulation System.

The following table outlines the essential differences with justifications for how the differences do not adversely impact the safety and effectiveness of the subject device.

Difference	Additional Details
The Katalyst Mark 1 has only 1 operation mode compared to many modes of the predicate devices	In order to provide a consistent and predictable training experience, the Katalyst Mark 1 only provide a single mode of operation.
Katalyst Mark 1's use of wireless communication between the controller device and the impulse generator.	In order to better utilize modern interfaces alongside with strong and robust platforms. Katalyst utilizes a Bluetooth Smart connection between its interface controller and the Impulse Pack. This is similar to the PowerDot Pd-01 Muscle Stimulator (with PowerDot Mobile Application) (K150078)
Patient Override Control	The Katalyst Mark 1 is always operated by an Katalyst operator for a patient, and as such the operator can immediately turn off the device.
Automatic No-Load Trip	The Katalyst Mark 1 is always operated by an Katalyst operator for a patient. The Operator's Guide outlines proper no load procedures.

Table 014- 4 Justification of differences with predicate devices

10.Non-Clinical Tests

The following non-clinical testing was provided in this 510(k):

10.1. Biocompatibility Testing

Skin contacting Katalyst Suit Base Layers have been tested to ISO 10993-10:2009 and ISO 10993-5:2009 standard under GLP.

10.2. Software Verification and Validation

Impulse Pack firmware and Katalyst Application software documentation, consistent with a Moderate level of concern, is provided with this 510(k).

System Validation Testing proves that all software requirement specifications were met and all software hazards were mitigated to Accepted risk level.

10.3. Electrical Safety and Electromagnetic Compatibility Testing

The Katalyst Suit and the Impulse Pack have been designed to comply and tested for compatibility with the applicable clauses of the following FDA-recognized standards:

- IEC/EN 60601-1:2005 "Medical Electrical Equipment - Part 1: General Requirements for Safety" Edition 3.1

- IEC 60601-2-10:2012 "Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators." Edition 2.0

- IEC/EN 60601-1-2:2014 "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Disturbances. Edition 4.0

10.4. Battery Testing

The Lithium-Polymer battery used in the Impulse Pack was tested by the battery manufacturer for compliance with IEC 62133 Edition 2.0.

10.5. Engineering Bench Testing

In addition to the full system validation testing, the 510(k) also included testing in accordance with the recommendations of FDA's "*Guidance Document for Powered Muscle Stimulator 510(k)s*" issued on June 9, 1999. Oscilloscope tracings were obtained of the device output waveforms under maximum supported voltage and pulse widths under loads of 500 Ω, 2 kΩ and 10 kΩ. Also, several system validation testing scenarios covering mitigation of wireless risks in accordance with FDA's "*Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff*" were added to our full system testing protocol.

11.Conclusion

Test results demonstrate the Katalyst Mark 1 Muscle Stimulation System is substantially equivalent to the predicate devices.