February 3, 2020

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

Re: K190966
Trade/Device Name: Katalyst Training System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: January 30, 2020
Received: January 31, 2020

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/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 Vivek Pinto, Ph.D.
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)*
K190966

Device Name
Katalyst Training System

Indications for Use *(Describe)*
The Katalyst Training System is an Over-The-Counter device intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only.

The Katalyst Training System 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 Training System's electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of motoneurons 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.

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 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitted by:

Katalyst Inc.
1201 3rd Avenue
Suite 2200
Seattle WA, 98101

Contact Person:

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

Date Summary Prepared

April 3, 2019

Trade/Proprietary Name

Katalyst Training System

Common Name

Powered Muscle Stimulator for Muscle Conditioning

Classification Name

Powered Muscle Stimulator

Product Code:

Powered Muscle Stimulator, For Muscle Conditioning – 21 CFR 890.5850
Product Code NGX
Review Panel: 89, Physical Medicine

Regulatory Class

Class II

Predicate Devices

Compex Wireless USA (K170903)

Device Description

The Katalyst Training System is a battery powered muscle stimulator that uses electrical muscle stimulation (EMS) technology to stimulate your muscles and help to improve muscle performance. Specifically, it uses neuromuscular electrical stimulation (NMES) to stimulate motor nerves, creating a muscle contraction to recruit more muscle fibers while training.

It is designed to be used with the Katalyst Application, which is the interface between the user and the Impulse Pack and runs on a user supplied iOS device. The iOS device communicates wirelessly with the Impulse Pack using Bluetooth 4.2.

Indications for Use

The Katalyst Training System is an Over-The-Counter device intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only.

The Katalyst Training System 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 Training System's electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of motoneurons 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.

Comparison to the Predicate Device

The similarities and differences between the technology and specifications of the subject device and its predicate devices are reflected below:

Basic Device Characteristics - Comparison with Predicate Devices

Characteristic	New Device	Predicate Device	Comparison
Manufacturer	Katalyst Inc.	DJO LLC	N/A
Device name, model	Katalyst Training System Model 1	Compex Wireless USA	N/A
Classification name	Powered muscle stimulator	Powered muscle stimulator	Similar
Product code	NGX	NGX	Similar
Regulation number	21 CFR 890.5850	21 CFR 890.5850	Similar
Panel	Physical Medicine	Physical Medicine	Similar
Class	Class II	Class II	Similar
510(k) number	-	K170903	N/A
Prescription/OTC	OTC	OTC	Similar
Indications for use	The Katalyst Training System is an Over-The-Counter device intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only. The Katalyst Training	The Compex Wireless USA is an Over-The-Counter device intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only. The Compex Wireless USA	Similar The Katalyst Training System does not include TENS

	System 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 Training System's electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of motoneurons 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.	is not intended for adjunctive therapy in the treatment of medical diseases and conditions of any kind. None of the Compex Wireless USA stimulation programs are designed for injured or disease afflicted muscles. Its use on such muscles is contraindicated. The work imposed on the muscles by the Compex Wireless USA programs is definitely not suitable for rehabilitation and physiotherapy. The Compex Wireless USA electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of motoneurons 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 Compex Wireless USA may therefore be considered a technique of muscle training. The Compex Wireless USA TENS is used for: • temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities. • the symptomatic relief and management of chronic, intractable pain and relief of	

		pain associated with arthritis.	
Target population	It is to be used by adults only.	It is to be used by adults only.	Similar
Connection of device to electrodes	The Impulse Pack connects to the Suit through output cables that terminate with pogo pin connectors. The Suit contains an embedded cable harness which makes connection with the built-in electrodes. Neither the cable harness or the electrodes are removable. The Suit also features leads with snap connectors for connecting to the arm electrodes	Lead wires Stimulation Module is directly connected to the custom Compex female SNAP assembled in the electrode. User Interface (LCD and buttons) is physically separated (Remote Control) and communicates wirelessly with up to four (4) Stimulation Modules. Stimulation safety remains fully managed by Stimulation Module electronic circuit itself.	Different
Power source(s)	Lithium Polymer (Li-Po) rechargeable battery 7.4V, 2,050 mAh	Remote: Lithium Polymer (LiPo) rechargeable 3.7[V] / ≥ 1500[mAh Stimulation Modules: Lithium Polymer (LiPo) rechargeable 3.7[V] / ≥ 450[mAh]	Similar
Method of line current isolation	N/A (battery operated device)	N/A (battery operated device)	Similar
Patient leakage current	N/A (battery operated device)	N/A (battery operated device)	Similar
Normal condition	N/A (battery operated device)	N/A (battery operated device)	Similar
Single fault condition	N/A (battery operated device)	N/A (battery operated device)	Similar
Number of output modes	One (NMES)	Two (NMES/TENS)	Different The Katalyst Training System does not include TENS
Number of output channels	13	4	Different Compex Wireless USA Electrodes can be applied to multiple anatomical sites. Katalyst Training

			System electrodes are fixed in the suit only allowing stimulation to predefined areas of the body.
- Synchronous or alternating?	Synchronous, but never 2 channels activated at the same time	Synchronous, but never 2 channels activated at the same time	Similar
- Method of channel isolation	Multi-Channel High Voltage Analog Switches. Except during channel activation, each channel is always in high Z state	Each channel is the middle of a H- Bridge. Except when it is activated, each channel is always in high impedance state	Similar
Regulated current or regulated voltage?	Regulated current (all channels)	Regulated current (all channels)	Similar
Software/firmware/microprocessor control?	Yes	Yes	Similar
Automatic overload trip?	Yes	Yes	Similar
Automatic no-load trip?	Yes	Yes	Similar
Automatic shut off?	"On/Off" switch	"On/Off" switch	Similar
Patient override control?	Yes	Yes, push on On/Off button directly pause the program	Similar
Indicator display - on/off status?	Yes	Yes	Similar
- Low battery?	Yes	Yes	Similar
- Voltage/current level?	Yes	Yes, unit = [Energy]	Similar
Timer range (minutes)	Maximum program: 60 minutes	Not publicly available	Cannot determine
Compliance with voluntary standards?	Yes IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Yes IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	Similar The Katalyst Training System is not intended for use in a home care environment
Compliance with 21 cfr 898?	Yes	Yes	Similar
Weight	Impulse Pack - 248 g	- Remote: 110 [g] - Stimulation Module:2x60 [g] - Docking Station 800 [g]	Similar

Dimensions	Impulse Pack – 148x78 mm Connector 1 – 65x32mm Connector 2 – 56x32mm	Not publicly available	Cannot determine
Housing material and construction	Plastic injection molding	Not publicly available	Cannot determine

Output Specification - Comparison with Predicate Devices

Characteristic	New Device	Predicate Device	Comparison
Manufacturer	Katalyst Inc.	DJO LLC	N/A
Device name, model	Katalyst Training System Model 1	Compex Wireless USA	N/A
Waveform	Endurance: Symmetrical Biphasic Resistance: Symmetrical Biphasic Strength: Symmetrical Biphasic Explosive Strength: Symmetrical Biphasic Potentiation: Symmetrical Biphasic Training Recovery : Symmetrical Biphasic Competition Recovery: Symmetrical Biphasic Warmup: Symmetrical Biphasic Muscle Relaxation: Symmetrical Biphasic	-Endurance: Symmetrical Biphasic -Resistance: Symmetrical Biphasic -Strength: Symmetrical Biphasic -Explosive Strength: Symmetrical Biphasic -Potentiation: Symmetrical Biphasic -Training Recovery (same as Active Recovery): Symmetrical Biphasic -Competition Recovery (same as Recovery Plus): Symmetrical Biphasic -Pre-Warmup Program: Symmetrical Biphasic -Muscle Relaxation (same as Massage): Symmetrical Biphasic -Pain relief TENS (same as FM): Balanced, asymmetrical Biphasic	Similar The Katalyst Training System does not include TENS
Shape	Endurance: Rectangular	-Endurance: Rectangular	Similar The Katalyst

	Resistance: Rectangular Strength: Rectangular Explosive Strength: Rectangular Potentiation: Rectangular Training Recovery : Rectangular Competition Recovery: Rectangular Warmup: Rectangular Muscle Relaxation: Rectangular	- Resistance: Rectangular -Strength: Rectangular -Explosive Strength: Rectangular -Potentiation: Rectangular -Training Recovery: Rectangular -Competition Recovery: Rectangular -Pre-Warmup: Rectangular -Muscle Relaxation: Rectangular -Pain relief TENS (same as FM):	Training System does not include TENS
Maximum output voltage (+/- 10%)	Endurance: 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ Resistance: 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ Strength: 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ Explosive Strength: 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ Potentiation: 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ	Endurance: 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ Resistance: 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ Strength: 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ Explosive Strength: 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ Potentiation: 60 V @ 500 Ω 152 V @ 2 kΩ 136 V @ 10 kΩ	Different The Katalyst Training System's max voltage is less than that of the predicate device The Katalyst Training System does not include TENS

	Training Recovery : 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ Competition Recovery: 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ Warmup: 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ Muscle Relaxation: 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ	Training Recovery: 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ Competition Recovery: 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ Pre Warmup: 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ Muscle Relaxation: 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ Pain Relief TENS: 180[V] peak on 10[kΩ] 170[V] peak on 2[kΩ] 58[V] peak on 500[Ω]	
Maximum output current (+/- 10%)	Endurance: 120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ Resistance: 120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ Strength: 120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ Explosive Strength: 120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ Potentiation: 120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ Training Recovery : 120 mA @ 500 Ω	Endurance: 116 mA @ 500 Ω 80 mA @ 2 kΩ 15 mA @ 10 kΩ Resistance: 116 mA @ 500 Ω 80 mA @ 2 kΩ 17 mA @ 10 kΩ Strength: 113 mA @ 500 Ω 80 mA @ 2 kΩ 15 mA @ 10 kΩ Explosive Strength: 81 mA @ 500 Ω 81 mA @ 2 kΩ 15 mA @ 10 kΩ Potentiation: 117 mA @ 500 Ω 80 mA @ 2 kΩ 16 mA @ 10 kΩ Training Recovery: 116 mA @ 500 Ω	Different The Katalyst Training System's max current is similar, but currents at 2 kΩ and 10 kΩ load resistances are less than that of the predicate device The Katalyst Training System does not include TENS

	50 mA @ 2 kΩ 10 mA @ 10 kΩ Competition Recovery: 120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ Warmup: 120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ Muscle Relaxation: 120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ	81mA @ 2 kΩ 16 mA @ 10 kΩ Competition Recovery: 116 mA @ 500 Ω 81 mA @ 2 kΩ 16 mA @ 10 kΩ Pre Warmup: 116 mA @ 500 Ω 81 mA @ 2 kΩ 15 mA @ 10 kΩ Muscle Relaxation: 116 mA @ 500 Ω 81 mA @ 2 kΩ 16 mA @ 10 kΩ Pain Relief TENS: 18[mA] peak @10[kΩ] 86[mA] peak@2[kΩ] 116[mA] peak@500[Ω]	
Pulse width	Potentiation: 250 to 375 µs Endurance: 250 to 375 µs Resistance: 250 to 375 µs Strength: 250 to 375 µs Explosive Strength: 250 to 375 µs Training Recovery : 250 to 375 µs Competition Recovery: 250 to 375 µs Warmup: 250 to 375 µs Muscle Relaxation: 250 to 375 µs	Endurance: 200 to 400 [µs] Resistance: 200 to 400 [µs] Strength: 200 to 400 [µs] Explosive Strength: 200 to 400 [µs] Potentiation: 200 to 400 [µs] Training Recovery: 200 to 400 [µs] Competition Recovery: 200 to 400 [µs] Pre Warmup: 200 to 400 [µs] Muscle Relaxation: 200 to 400 [µs] Pain Relief TENS: 70 to 300[µs] (measured at	Similar The Katalyst Training system's pulse width range is a subset of that of the predicate device's. The Katalyst Training System does not include TENS.

		50% of positive pulse)	
Frequency	Endurance: 10 Hz Resistance: 50 Hz Strength: 75 Hz Explosive Strength: 105 Hz Potentiation: 1 to 75 Hz Training Recovery : 1 to 9 Hz Competition Recovery: 1 to 6 Hz Warmup: 5 Hz Muscle Relaxation: 1 Hz	Endurance: 10 [Hz] Resistance: 50 [Hz] Strength: 75 [Hz] Explosive Strength: 100 [Hz] Potentiation: From 1 to 75 [Hz] Training Recovery: 10 [Hz] Competition Recovery: 0.5 [Hz] Pre Warmup: 4 [Hz] Muscle Relaxation: 1 [Hz] Pain Relief TENS: 5 to 122[Hz]	Similar The Katalyst Training System does not include TENS
Phase duration	250 to 375 µs	Not publicly available	Cannot determine
Net charge	Endurance: 0 µC @ 500 Ω Resistance: 0 µC @ 500 Ω Strength: 0 µC @ 500 Ω Explosive Strength: 0 µC @ 500 Ω Potentiation:	Endurance: 0 [µC] @ 500Ω Excitation pulse fully compensated Resistance: 0 [µC] @ 500Ω Excitation pulse fully compensated Strength: 0 [µC] @ 500Ω Excitation pulse fully compensated Explosive Strength: 0 [µC] @ 500Ω Excitation pulse fully compensated Potentiation: 0 [µC] @ 500Ω Excitation	Similar Katalyst Training System does not include TENS

	0 µC @ 500 Ω Training Recovery : 0 µC @ 500 Ω Competition Recovery: 0 µC @ 500 Ω Warmup: 0 µC @ 500 Ω Muscle Relaxation: 0 µC @ 500 Ω	pulse fully compensated Training Recovery: 0 [µC] @ 500Ω Excitation pulse fully compensated Competition Recovery: 0 [µC] @ 500Ω Excitation pulse fully compensated Pre Warmup: 0 [µC] @ 500Ω Excitation pulse fully compensated Muscle Relaxation: 0 [µC] @ 500Ω Excitation pulse compensated Pain Relief TENS: 0 [µC] @ 500Ω Excitation pulse fully compensated	
Maximum phase charge	45 µC @ 500 Ω	48 [µC] @ 500Ω	Similar
Maximum current (rms) density	1.15 mA/cm2 @ 500 Ω	4.8 [mA/cm2] @ 500Ω	Different The Katalyst Training System Maximum Current (RMS) Density is lower than that of the predicate device
Maximum Power Density (using smallest electrode conductive surface area)	22.68 mW/cm2 @ 500Ω	27.6 [mW/cm2] @ 500Ω	Similar
Pulses per burst	4 - 420	Not publicly available	Cannot determine
Bursts per second	0.125	Not publicly available	Cannot determine
Burst duration (seconds)	4	Not publicly available	Cannot determine
Duty Cycle	50%	Not publicly available	Cannot determine
ON time (seconds)	4	Not publicly available	Cannot

			determine
OFF time (seconds)	4	Not publicly available	Cannot determine

Although there are minor differences observed between the Katalyst Training System and the predicate device, no difference found raised any question regarding safety and effectiveness of the new device.

Standards

The Katalyst Training System is designed and manufactured in accordance with the following standards:

- AAMI/ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1, Mod.)

- IEC 60601-1-2 Edition 4.0 2014-02 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests

- IEC 60601-2-10 Edition 2.1 2016-04 Medical Electrical Equipment - Part 2-10: Particular Requirements for The Basic Safety and Essential Performance of Nerve and Muscle Stimulators

- 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 [Including: Corrigendum 1 (2013)]

- ISO 14971 Second Edition 2007-03-01 Medical Devices - Application of Risk Management to Medical Devices

- ISO 10993-5 Third Edition 2009-06-01 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity

- ISO 10993-10 Third Edition 2010-08-01 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization

- AAMI /ANSI /IEC 62304:2006/A1:2016 Medical Device Software - Software Life Cycle Processes [Including Amendment 1 (2016)]

Non-Clinical Testing

The Katalyst Training System was subjected to testing in accordance with the appropriate standards and the results are provided in this 510(k). The non-clinical tests performed are as follows:

- Biocompatibility Testing
    - The Skin contacting Base Layers have been tested to ISO 10993-5 and ISO 10993-10 standard under GLP.

- Software Verification and Validation
    - The Impulse Pack firmware and Katalyst Application were verified in accordance with the requirements of FDA's guidance document: General Principles of Software Validation. This testing proves that all software requirement specifications were met.

- Battery Testing
    - The Lithium-Polymer battery used in the Impulse Pack was tested by the battery manufacturer for compliance with IEC 62133

- 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.

- Electrical Safety and Electromagnetic Compatibility:
    - The Katalyst Training System has been tested to AAMI/ANSI ES60601-1, IEC 60601-1-2, and IEC 60601-2-10.

- Wireless Coexistence Testing:
    - The performance of the Katalyst Training System was evaluated in an environment with other Katalyst Training Systems and with other types of 2.4 GHz wireless devices (Bluetooth and Wi-Fi). The device met all specified requirements.

Clinical Testing

No clinical studies are submitted to support this premarket notification submission.

Conclusion

Test results demonstrate the Katalyst Training System is substantially equivalent to the predicate device.