November 27, 2020

DJO, LLC
Michael Davis
Regulatory Affairs Consultant
1430 Decision Street
Vista, California 92081

Re: K201653
Trade/Device Name: Compex® Sport Elite 3.0
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX, NUH, NYN
Dated: June 16, 2020
Received: June 18, 2020

Dear Michael Davis:

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,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
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)*
K201653

Device Name
Compex® Sport Elite 3.0

Indications for Use *(Describe)*
EMS: The Compex Sport Elite 3.0 is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The work imposed on the muscles by the Compex Sport Elite 3.0 programs is not suitable for rehabilitation or physiotherapy.

TENS: The Compex Sport Elite TENS is intended 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.

The Compex Sport Elite 3.0 is an Over-the-Counter device to be used by adults 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 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is K201653.

Submitted by:	DJO, LLC 1430 Decision Street Vista, CA 92081 FDA Establishment Registration: 2020737
Contact Person:	Michael Davis Regulatory Affairs Site Lead (205) 789-8154
Date Summary Prepared:	November 24, 2020
Trade Name:	Compex® Sport Elite3.0
Common Name:	Stimulator, Muscle
Classification Name:	Stimulator, muscle, powered (21CFR890.5850) Stimulator, Nerve, Transcutaneous (21 CFR 882.5890)
Product Code:	Powered Muscle Stimulator, For Muscle Conditioning – 21 CFR 890.5850; Product Code NGX; Review Panel: Physical Medicine (primary product code) Stimulator, Nerve, Transcutaneous, Over-The-Counter- 21 CFR 882.5890; Product Code NUH; Review Panel: Neurology Stimulator, Electrical, Transcutaneous, For Arthritis 21 CFR 890.5850; Product Code NYN (subsequent code); Review Panel: Neurology
Regulatory Class:	Class II
Predicate Device:	Compex Sport Elite (K170918) - ClassII (Manufacturer's own predicate device)

Device Description:

The Compex Sport Elite 3.0 is an electrical stimulation device, which stimulates healthy muscles by means of electrical impulses transmitted by electrodes. The electrical pulses generated by the Compex Sport Elite 3.0 stimulates motor nerves to stimulate a muscular response. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, and totalsession duration), different types of muscle work can be imposed on the stimulated muscles. The Compex Sport Elite 3.0 may therefore be considered a technique of muscletraining.

TENS (Transcutaneous Electrical Nerve Stimulation) and NMES (NeuroMuscular Electrical Stimulation) target different nerve groups of the body. TENS specifically targets the sensory nerves, which are responsible for sending pain signals to the brain. NMES targets the muscle itself, specifically through the motor nerves. This allows the NMES machine to create a muscle contraction to recruit more muscle fibers when training; warming up or recovering.

The Compex Sport Elite 3.0 system consists of these components:

- 1x Stimulator
- 1x Lead WireSet
- 2x Small Performance Snap Electrodepackages
- 2x Large Performance Snap Electrodepackages
- 1x Charging Cable
- 1x Carrying Case

These components are packaged together in a carrying case along with the user guide and a battery charger.

The electrodes are supplied by Axelgaard Mfg. Co., Inc. and cleared under K130987.

The stimulator is a microprocessor controlled 4-channel electro-stimulator. The stimulator drives each output channel independently based upon the parameters pre-defined for a program selected by the user. The user operates the device through a User Interface (UI) consisting of a graphic LCD, keypad controls and supporting software. The User Interface is made up of different menus that allow the following functions: set up the device (Options Menu), select a desired category (Category Menu), select a preset program (Treatments´ Menu), tune a selected program (Stimulation Menu), andadjust the stimulation intensities (Level Menu).

See Appendix 5 Illustrated Device Description for a detailed description.

Indications for Use:

EMS: The Compex Sport Elite 3.0 is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The work imposed on the muscles by the Compex Sport Elite 3.0 programs is not suitable for rehabilitation or physiotherapy.

TENS: The Compex Sport Elite 3.0 TENS is intended 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.

The Compex Sport Elite 3.0 is an Over-the-Counter device to be used by adults only.

Summary of Non-clinical Tests:

The subject device has been evaluated for safety and performance by lab bench testing in accordance with the following standards:

1. ANSI/AAMI 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 60601-1:2005, MOD)
2. ANSI/AAMI/IEC 60601-1-2:2014, Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
3. IEC 60601-1-6 Edition 3.1 2013-10, Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
4. IEC 60601-1-11 Edition 2.0 2015-01, 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
5. 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
6. IEC 62133-2 Edition 1.0 2017-02, 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 - Part 2: Lithium Systems
7. ANSI/AAMI/IEC 62304:2006/A1:2016, Medical Device Software - Software Life Cycle Processes [Including Amendment 1 (2016)]

Comparison to the Predicate Device and Conclusion:

The changes do not affect the intended use and do not alter the fundamental scientific technology of the predicate device; Compex Sport Elite (K170918). The subject device Compex Sport Elite 3.0 technological characteristics, features, specifications, materials, mode of operation and intended use are substantially equivalent to the predicate device named above. The differences between the subject device and predicate device do not raise new issues of safety or effectiveness.

The subject device has undergone testing by a Nationally Recognized Test Laboratory, Nemko Shanghai Ltd. Shenzhen Branch, to assure safety and conformance to standards for Electromagnetic Compatibility. Further, the subject device conforms to existing design controls procedures per §820.30. Below is a comparison analysis between the subject and predicate devices:

Table 1 Comparison Analysis

No	Characteristic	Predicate Device	Subject Device	Same/ Similar/ Different	Risk Analysis (HAZ-PRO-130)
1	Electrodes connection	Lead wires 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.	Lead wires 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.	Same	No additional risk.
2	Power Source	Rechargeable Ni-MH battery 4.8V (4 cells AA=R6); replaceable.	Rechargeable Li-ion. battery 3.7V (one cell); not replaceable.	Different	Smaller size; reduced weight. User will not handle battery. The battery conforms to IEC 62133-2 and UN DOT 38.3. No additional risk
3	Battery Charger Regulation	Discrete components with MCU regulate the battery charging	Independent charging IC to regulate battery charging with protection monitor.	Different	Subject device utilizes an independent charging IC to perform protection work during charging or discharging process, this reduces MCU involvement in regulation and simplifies the design. No additional risk

No	Characteristic	Predicate Device	Subject Device	Same/ Similar/ Different	Risk Analysis (HAZ-PRO-130)
4	Transformer	1. Input voltage: 4.8V 2. Size: EFD15 3. N1: 2.7uH, N2: 350uH 5. Output power: 10W	1. Input voltage: 3.7V 2. Size: EFD15 (same) 3. N1: 2.6uH, N2: 650uH 5. Output power: 10W(same)	Similar	Same mechanical structure and output. Lower input voltage (3.7V) of subject device leads to the input current and inductance value increase to achieve the same output power. No additional risk.
5	Number of Output Modes	Two (NMES/TENS)	Two (NMES/TENS)	Same	No additional risk.
6	Power Adapter	DC jack male charging port, 9V/400mA power adapter	Micro-USB male charging port, 5V/2A USB power adapter or PC	Different	1. The subject device provides the Micro-USB charging port which allows to connect to USB power adapter or PC (user convenience) 2. USB charging is more reliable method which reduces hazard ID1.2.15 'battery overcharging'. 3. No additional risk.
7	Number of Output Channels	Four	Four	Same	No additional risk.
8	LCD	1. LCD type: Mono STN LCD, 128 * 64pixel 2. Data Bus: 8-Bits Bus by MCU system bus 3. Backlight: 2 serial 3 parallel (total 6 LEDs)	1. LCD type: Color TFT LCD, 320 * 240 pixel 2. Data Bus: 16-Bits Bus by special LCD 8080 port 3. Backlight: 4 Parallel LEDs	Different	1. The backlight are LEDs 2. The drive and control method all are PWM technology 3. The method for max current limiting for LED are all same by hardware 4. TFT display has better performance on resolution and viewing angle than

No	Characteristic	Predicate Device	Subject Device	Same/ Similar/ Different	Risk Analysis (HAZ-PRO-130)
					STN display of predicate device. Other characters of LCD are same for predicate device and subject device. No additional risk.
9	LED Indicator	No LEDs for User Interface	1. LED: Five indicating LEDs, four are for channel buttons and the other one is for central confirmation button. 2. LED Drive &Power: 5V Power supply with lightadjusting	Different	1. Common LED 2. The drive circuit limits the max current of LED lower than 20mA in hardware. Software PWM adjusts the LED brightness. No additional risk
10	Synchronous Or Alternating	Synchronous, but never 2 channels activated at the same time	Synchronous, but never 2 channels activated at the same time	Same	No additional risk
11	Method of Channel Isolation	Each channel is the middle of an H-Bridge. Except when it is activated, each channel is always in high impedance state.	Each channel is the middle of an H-Bridge. Except when it is activated, each channel is always in high impedance state.	Same	No additional risk
12	Regulated Current or Regulated Voltage	Regulated current (all channels)	Regulated current (all channels)	Same	No additional risk
13	Software Microprocessor Control	Yes	Yes	Same	No additional risk

No	Characteristic	Predicate Device	Subject Device	Same/ Similar/ Different	Risk Analysis (HAZ-PRO-130)
14	Automatic Overload Trip	Yes	Yes	Same	No additional risk
15	Automatic No-Load Trip	Yes	Yes	Same	No additional risk
16	Automatic Shut Off	"On/Off" switch	"On/Off" switch	Same	No additional risk
17	Patient Override Control	Yes, push on On/Off button directly pauses the program	Yes, push on On/Off button directly pauses the program	Same	No additional risk
18	Indicator Display - On/Off Status	Yes	Yes	Same	No additional risk
19	Indicator Display - Low Battery Detection	Yes	Yes	Same	No additional risk
20	Indicator Display Voltage /Current Level	Yes, unit = [Energy] The Max/Min level showed on display is 999/0	Yes, unit = [Energy] The Max/Min level showed on display is 999/0	Same	No additional risk
21	Timer Range (minutes)	Yes, unit= [seconds], max = 55 [minutes]	Yes, unit= [seconds], max = 55 [minutes]	Same	No additional risk
22	Housing Materials and Construction	Casing: Plastic (ABS, with PMMA on the windows) Buttons: Silicon rubber ABS housing around the battery cells Battery contacts: SK5 steel	Casing: Plastic (ABS, with PMMA on the windows) Buttons: Plastic ABS Silicone sleeve: Silicone + Gas phase glue	Similar	1. Silicone sleeve is designed to meet IP22. 2. uses biocompatible materials used on other devices 3. No additional risk
23	Dimensions	142*99*36mm	Without silicone sleeve: 136mm*76mm*21mm With silicone sleeve: 140mm*80mm*24.6mm	Different	Subject device is more compact. No additional risk

No	Characteristic	Predicate Device	Subject Device	Same/ Similar/ Different	Risk Analysis (HAZ-PRO-130)
24	Ingress Protection	IP20	IP22	Different	IP22 is required by IEC 60601-1-11. Reduced risk.
25	Type of Charging Port	DC Jack female charging port	USB type-A customized 5 pin female connector	Different	1. The subject device provide customized charging port which reduces the occurrence of hazard ID 1.1.11 'incorrect connection terminals' 2. No additional risk
26	BOSS feature	Yes	Yes	Same	No additional risk
27	Part number of MCU	Renesas: M30620SPGP, up to 24Mhz, RAM 10K (External ROM 512K) VCC= 3V and 5V, LQFP100	ST: STM32F103VCT, 32bit up to 72Mhz, RAM 48K ROM 256K, VCC= 3V, LQFP100	Different	The performance of ARM MCU of subject device is improved. No additional risk.
28	Data library	Shared with MCU ROM	External 64M bit SPI Flash memory	Different	The subject device stores a much larger data library in external flash memory. No additional risk
29	PCB	PCB layers: 4 layers Size: 75mm * 120mm * T:1.6mm1: Surface treatment: gold plating Flammability rating: UL 94V0	PCB layers: 4 layers Size: 72mm * 125mm *T:1.6mm Surface treatment: gold plating Flammability rating: UL 94 V0	Similar	The only difference is the PCB size. No additional risk.
30	Library Update Port	UART	USB	Different	The communication port is different, but the function is same. All with CRC verification. No additional risk.

Table 2 Output Specifications Comparison Analysis

No	Characteristic	Predicate Device	Subject Device	Same/ Similar/ Different	Risk analysis
31	Waveform	Symmetrical Biphasic	Symmetrical Biphasic	Same	No additional risk
32	Shape	Rectangular	Rectangular	Same	No additional risk
33	Maximum Output Voltage (±10%)	60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ	60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ	Same	No additional risk
34	Maximum Output Current (±10%)	120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ	120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ	Same	No additional risk
35	Pulse Width	NMES: 200 to 400 [µs] (microseconds) TENS: 70 to 300[µs] (measured at 50% of positive pulse)	NMES: 200 to 400 [µs] (microseconds) TENS: 70 to 300[µs] (measured at 50% of positive pulse)	Same	No additional risk
36	Frequency	1 to 120 Hz	1 to 120 Hz	Same	No additional risk
37	Net Charge [µC/pulse]	0 [µC] @ 500Ω Excitation pulse fully compensated	0 [µC] @ 500Ω Excitation pulse fully compensated	Same	No additional risk
38	Maximum Phase Charge [µC]	48 [µC] @ 500Ω	48 [µC] @ 500Ω	Same	No additional risk

No	Characteristic	Predicate Device	Subject Device	Same/ Similar/ Different	Risk analysis
39	Maximum Current Density [mA/cm2]	1.49 [mA/cm2] @ 500Ω	1.49 [mA/cm2] @ 500Ω	Same	No additional risk
40	Maximum Power Density [mW/cm2]	27.6 [mW/cm2] @ 500Ω	27.6 [mW/cm2] @ 500Ω	Same	No additional risk

Table 3 Software Comparison Analysis

No	Characteristic	Predicate Device	Subject Device	Same/ Similar/ Different	Risk Analysis
41	Dual MCU design Master MCU is used to control treatment program and user interface. Protection MCU is used tomonitor the operation of the Master MCU and thetreatment output.	Master MCU: M30620SPGP, up to 24Mhz, RAM 10K (External ROM 512K) VCC= 3V and 5V, LQFP100 Protection MCU: MSP430F1101	Master MCU: STM32F103VCT, 32bit, up to 72Mhz, RAM 48K ROM 256K, VCC= 3V,LQFP100 Protection MCU: MSP430F1101	Different master MCU Same protection MCU	Subject device's master MCU has improved performance for control and user interface. Same protection MCU is used. No additional risk.

No	Characteristic	Predicate Device	Subject Device	Same/ Similar/ Different	Risk Analysis
42	Development Environment	Boot: Renesas IDE Main firmware: Renesas IDE Protection system: IAR	Boot: IAR Main firmware: Keil Protection system: IAR	Similar	1. The functionalityof boot and main firmware for both devices are the same. 2. No additional risk
43	Software /Firmware Organization	Software is divided into Boot, Main Firmware.	Software is divided into Boot, Main Firmware, Libraries, Manufacturing and Branding Records, Live Records	Different	Subject device uses a more updated software organization tool. Reduced risk
44	Keyboard-Buttons design	Power ON button Information button 4 channel selection buttons. 4 up/down buttons for treatment strength adjustment	Power On button Five button guide wheel for information, user set up, and program strength adjustment. 4 channel selection buttons	Similar	Subject device offers easier user interaction. No additional risk.
45	UI Screens - Favorites screen	Does not exist	Allows user to set up favorites screen	Different	Subject device offers user a quicker device start. No additional risk.
46	UI Screens - Program screen	Allows user to select various user settings for the device, such as language, sound volume, display contrast, etc.	Allows user to select various user settings for the device, such as time, date, language, power saving mode, etc.	Similar	Subject device offers a better user experience. No additional risk.

No	Characteristic	Predicate Device	Subject Device	Same/ Similar/ Different	Risk Analysis
47	UI Screens - Placements selection screen	Does not exist, need reference to printed user guide	Using graphic display to inform user the proper location of the treatment electrode pads on a human body diagram.	Different	Subject device offers clearer usage guide. Reduced risk.
48	UI Screens - Level selection screen	5 treatment levels are selected by the up-down button and viewable on the display	5 treatment levels are selected by the guiding wheel and the viewable on the display	Same	No additional risk
49	UI Screens - Channels selection screen	Insert the treatment lead wire to the corresponding output port, then press the channel button to add corresponding channels.	Insert the treatment lead wire to the corresponding output port, then press the channel button to add corresponding channels.	Same	No additional risk
50	UI Screens - Stimulation screen	Text and graphic information	Text and graphic information	Similar	Subject device offers better treatment progress information to user. No additional risk
51	UI Screens - Stim pause screen and Stim completed screen	Text and graphic information	Text and graphic information	Similar	Subject device offers better treatment progress information to user. No additional risk
52	UI Screens - Setting screen	Offers sound, language, display contrast selection	Offers sound, language, power saving setting selection. Chinese is added.	Similar	Subject device offers better user experience. No additional risk
53	UI Screens - Charging screen	Uses an icon on the display to show the device battery charging progress.	Uses an icon on the display to show the device battery charging progress.	Same	No additional risk

No	Characteristic	Predicate Device	Subject Device	Same/ Similar/ Different	Risk Analysis
54	UI Screens - Electrode fault screen	Graphic and text information "display electrode fault symbol on screen, a twinkling arrow points to the fault channel"	Graphic and text information "display electrode fault symbol on screen, a twinkling arrow points to the fault channel, LED of fault channel flashes"	Similar	1. Subject device offers better user experience. 2. No additional risk
55	UI Screens -Low battery screen	Graphic and test information There is a battery icon to indicate the charge state (6 bars mean the battery is fully charged), if the battery icon contains just two bars, this means the power is running low, need to recharge the unit	Graphic and test information There is a battery icon to indicate the charge state (4 bars mean the battery is fully charged). 4 bars indicate full battery (4.0-4.2V) 3 bars indicate almost full (3.8-4.0V) 2 bars indicate half-empty (3.6-3.8V) 1 white bar indicates almost empty (3.5-3.6V) 1 red bar indicates empty(<3.5V)	Similar	1. Subject device offers better user experience. 2. No additional risk
56	Firmware & Library Update	Firmware and library can be updated from UART port in the factory or service center	Firmware and library can be updated from customized USB port in the factory or service center. Unit charging or upgrades use same USB port, which is convenient in production and upgrades is not available for user	Different	1.Subject device provides the USB data transmit connector which is keyed and can only be connected in one orientation and reduces the occurrence Hazard ID 1.1.11 'incorrect connection terminals' 2.User cannotupdate the firmware and library via USB port without permission

No	Characteristic	Predicate Device	Subject Device	Same/ Similar/ Different	Risk Analysis
					from manufacture, there is no impact on its safety and effectiveness. No additional risk
57	External Flash Library Data Structure	Does not exist	Uses external flash to store libraries to graphics, treatment program and multi language interface.	Different	Subject device offers better user experience. No additional risk
58	CRC verification for master MCU code	CRC algorithm is used for software integrity control.	CRC algorithm is used for software integrity control.	Same	No additional risk
59	Communication Protocol	UART communication protocol that is developed for the production software and device control	USB communication protocol that is developed for the production software and device control	Different	1. Both communication protocols are used for production purpose and do not impact safety and effectiveness on end users 2. Subject device uses USB communication protocol which is convenient to service personnel (reduces hazard ID 7.4.1 'bad or inadequate maintenance') 3. No additional risk

No	Characteristic	Predicate Device	Subject Device	Same/ Similar/ Different	Risk Analysis
60	Programs	Muscle Building 1-Endurance 2-Resistance 3-Strength 4-Explosive strength Warm Up & Recovery 5-Prewarm Up 6-Training recovery 7-Competition recovery 8-Muscle relaxation 9-Potentiation Pain Management 10-Pain Relief TENS	Muscle Building 1-Endurance 2-Resistance 3-Strength 4-Explosive strength Warm Up & Recovery 5-Prewarm Up 6-Training recovery 7-Competition recovery 8-Muscle relaxation 9-Potentiation Pain Management 10-Pain Relief TENS	Same	No additional risk
61	MSP430 Protect System Development Environment	IAR	IAR	Same	No additional risk
62	Protection System Report Error	12 error codes	13 error codes. The first 12 error codes are the same as predicate device. The No. 13th error code is to ensure both ST32 (main MCU) and MSP430 (protection system MCU) are working normally at the same time.	Similar	1. The new 13th error code is to check MCU working properly 2. No additional risk
63	CRC Verification of Protection System Code	CRC algorithm is used for software integrity control.	CRC algorithm is used for software integrity control.	Same	No additional risk