August 24, 2021

NCS Lab Srl
Matteo Mantovani
Technical Director- CEO
Via Pola Esterna 4/12
Carpi, Modena, Italy 41012

Re: K210674
Trade/Device Name: Shoulder Pacemaker™
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, KQX
Dated: May 18, 2021
Received: May 24, 2021

Dear Matteo Mantovani:

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,

Patrick Antkowiak, PhD
Assistant Director (Acting)
DHT5B: Division of Neuromodulation
and Rehabilitation 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)*
K210674

Device Name
Shoulder PacemakerTM

Indications for Use *(Describe)*
Shoulder PacemakerTM is an electrotherapy device intended for neuromuscular electrical stimulation (NMES).
The Indications for Use for Shoulder PacemakerTM are:
- Prevention or retardation of disuse atrophy;
- Muscle re-education;
- Maintaining or increasing range of motion.

The device is intended for 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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CERTIFIED QUALITY MANAGEMENT SYSTEM | UNI EN ISO 9001:2015 | UNI CEI EN ISO 13485:2016

510(k) Summary (21 CFR 807.92)

1 GENERAL INFORMATION

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Matteo Mantovani
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Date Prepared: 30,07,2021

2 DEVICE

Trade Name	Shoulder Pacemaker™
Common/Usual Name	Muscle Stimulator
Regulation Description (Regulation Number)	Powered Muscle Stimulator (21 CFR 890.5850) Goniometer, AC-powered (21 CFR 888.1500)
Device Class, Submission Type	Powered Muscle Stimulator Class II, 510(k) Goniometer AC-powered Class I, 510(k) exempt
Product Code	IPF, KQX
Review Panel	Physical Medicine, Orthopedic

3 PREDICATE DEVICE

	Brand Name	510(k) number	Manufacturer	Product code
Primary Predicate				
	CyMedica e-vive System; CY-1000	K163067	CyMedica Orthopedics, Inc	IPF, GZJ, KQX
Secondary Predicate				
	Chattanooga Revolution Wireless	K153696	DJO, LLC	IPF, GZJ

4 DEVICE DESCRIPTION

The Subject device, Shoulder Pacemaker, is a wearable muscle stimulator, powered by an internal battery, used for rehabilitation/physiotherapy purposes to produce muscle contraction, through the passage of electric current, by means of conductive electrodes positioned on the body area of interest, in patients with shoulder functional pathologies.

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The Shoulder Pacemaker device is intended to be used as a shoulder muscle stimulation tool to reduce and eliminate related functional pathologies.

The subject device can be used in stand-alone mode or in wireless mode.

The Shoulder Pacemaker should be used in combination with:

- conductive electrodes, that are applied directly to the patient's skin to ensure muscle electrostimulation;
- saver protection, interposed between the stimulator and the patient's arm.

The electrodes, identified to meet the requirements to be compatible accessories of the Subject device, are FDA cleared:

- "ValuTrode® Neurostimulation Electrodes" (K130987), made by Axelgaard manufacturing co., Ltd. Therefore, the biocompatibility aspects of these electrodes were already reviewed and cleared.

The device is equipped with a goniometer (product code KQX, Class I, 510 (k) exempt), which can record the acceleration and angular velocity data of the device and allows to estimate the movement of the subject's arm. In this way, the device automatically detects the elevation angle of the arm and based on that information it can modulate the electrical stimulation.

The Shoulder Pacemaker is a prescription device and is intended to be used following the directions of a healthcare provider; additionally, the device may be used in a healthcare facility setting or by a patient or lay operator in a home environment.

5 INDICATIONS FOR USE

Shoulder Pacemaker™ is an electrotherapy device intended for neuromuscular electrical stimulation (NMES).

The Indications for Use for Shoulder Pacemaker™ are:

- Prevention or retardation of disuse atrophy;
- Muscle re-education;
- Maintaining or increasing range of motion.

The device is intended for adults only.

6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The present 510(k) submission would demonstrate that the Shoulder Pacemaker results substantially equivalent to the following predicate devices:

- Primary Predicate: *CyMedica e-vive System; CY-1000*, which has been cleared through 510(k) application *K163067*
- Secondary Predicate: *Chattanooga Revolution Wireless*, which has been cleared through 510(k) application *K153696*

Multiple predicate devices, as listed above, have been identified, to support the substantial equivalence determination for the Shoulder Pacemaker; the Applicant would combine features from the two predicates with the same intended use into the subject device, to provide a complete muscle stimulator system, according to the user's needs.

Both the subject and the predicate devices are intended for the neuromuscular electrical stimulation (NMES). Although there are few minor differences, the indications for use of the Shoulder Pacemaker device can be considered as a subset of those of the predicates.

The predicate devices have additional features, functions, and applications that are not included in the Shoulder Pacemaker.

Concerning the technological characteristics, the following tables summarizes similarities and differences among the subject and the predicate devices. A discussion on the comparison about the technological characteristics, underlying that the differences do not raise any new questions of safety or effectiveness in the Shoulder Pacemaker, compared to the chosen predicates, is reported below the following tables.

Device Characteristic	**Subject device (This 510(k) Application)**	**Primary Predicate (PP)**	**Secondary Predicate (SP)**	**Comparison**
Manufacturer	NCS Lab Srl	CyMedica Orthopedics, Inc.	DJO, LLC	-
510(k) Number	Under present review	K163067	K153696	-
Device Name, Model	Shoulder Pacemaker	e-vive System; CY-1000	Chattanooga Revolution Wireless	-
Classification Regulation	890.5850 888.1500	890.5850 888.1500 882.5890	890.5850 882.5890	Subset to PP and SP
Product Code	IPF: Powered Muscle Stimulator KQX: Goniometer AC-powered	IPF: Powered Muscle Stimulator KQX: Goniometer AC-powered GZJ: Stimulator, Nerve, Transcutaneous, For Pain Relief	IPF: Powered Muscle Stimulator GZJ: Stimulator, Nerve, Transcutaneous, For Pain Relief	Same main product code to PP and SP Subset to PP and SP
Class	II	II	II	Same
Primary Function	Shoulder Pacemaker is an electrotherapy device intended for neuromuscular electrical stimulation (NMES).	The CyMedica e-vive System is a multifunctional electrotherapy device that allow for neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS).	The Chattanooga® Revolution Wireless is a neuromuscular electrical stimulation (NMES) device, which stimulates nerve fibers by means of electrical impulses transmitted by electrodes and transcutaneous	Same

Device Characteristic	Subject device (This 510(k) Application)	Primary Predicate (PP)	Secondary Predicate (SP)	Comparison
			electrical nerve stimulation (TENS).	
Indication for Use	Shoulder Pacemaker™ is an electrotherapy device intended for neuromuscular electrical stimulation (NMES). The Indications for Use for Shoulder Pacemaker™ are: - Prevention or retardation of disuse atrophy; - Muscle re-education - Maintaining or increasing range of motion. The device is intended for adults only.	The CyMedica e-vive System is a multifunctional electrotherapy device with two treatment modes that allow for neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS). Indications for Use: - As an NMES device, indications are for the following conditions: - Relaxation of muscle spasms - Retardation or prevention of disuse atrophy - Increasing local blood circulation - Re-educating muscles - Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis - Maintaining or increasing range of motion As a TENS device, indications are for the following conditions: - Symptomatic relief and management of chronic intractable pain - Adjunctive treatment for post-surgical and post-trauma acute pain.	The Chattanooga Revolution Wireless is a clinical electrotherapy device intended for use under the supervision of a Healthcare Professional. Indications for Use: As an NMES device, indications are for the following conditions: - Retarding or preventing disuse atrophy - Maintaining or increasing range of motion - Re-educating muscles - Relaxation of muscle spasms - Increasing local blood circulation - Prevention of venous thrombosis of the calf muscles immediately after surgery As a TENS device, indications are for the following conditions: - Symptomatic relief and management of chronic, intractable pain - Post-surgical and post-trauma acute pain As a pulsed mode device, indications are for the following conditions: - Relaxation of muscle spasm - Increasing local	Same intended use to PP and SP Subset Indications for use with respect to PP and SP

Device Characteristic		Subject device (This 510(k) Application)	Primary Predicate (PP)	Secondary Predicate (SP)	Comparison
				blood circulation - Retardation or prevention of disuse atrophy - Maintenance or increase of range of motion.	
Basic Unit Characteristics					
Power Source(s)		Rechargeable Li-ion battery, 3.7V / 550 mAh 1.01 x 1.67 x 0.25 (in)	Single VD434053: 3.7V; 1000mAh; Lithium-ion polymer battery	Remote control battery: Rechargeable 3.7[V] / ≥ 1,500[mAh] lithium polymer (LiPo) battery. Module battery: Rechargeable 3.7[V] / ≥ 450[mAh] lithium polymer (LiPo) battery.	Similar Note 1
Method of Line Current Isolation		N/A Battery operated device	No line connection	N/A Battery operated device	Same Note 1
Patient Leakage Current	**Normal condition (µA)**	N/A Battery operated device	4.88	N/A Battery operated device	Same to SP Note 1
	Single fault condition (µA)	N/A Battery operated device	8.00	N/A Battery operated device	Same to SP Note 1
Average DC current through electrodes when device is on but no pulses are being applied (µA)		<0.01µA	N/A	N/A	Different Note 1
Number of Output Modes		1	3	Muscle stimulator: Electrodes	Different Note 2
Number of Output Channels		1	2	4	Different Note 2
● **Synchronous or Alternating?**		N/A	Alternating	See Output Specifications Below *(*Ref. *510(k) summary* - K153696)	
● **Method of Channel Isolation**		N/A	Transistor	Each channel is the middle of a H Bridge. Except when it is activated, each channel is always in high impedance state	

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Regulated Current or Regulated Voltage?		Regulated power	Regulated power	Regulated current on all channels	Same to PP Note 3
Software/Firmware/ Microprocessor Control?		Yes	Yes	Yes	Same
Automatic Overload Trip?		No	No	Yes	Same to PP Note 3
Automatic No-Load Trip?		No	No	Yes	Same to PP Note 3
Automatic Shut Off?		Yes	Yes	Yes, On/Off switch	Same
Patient Override Control?		Yes	Yes Stop Buttons	Yes	Same
Indicator Display:	**On/Off Status?**	Yes	Yes	Yes	Same
	Low Battery?	Yes	Yes	Yes	Same
	Voltage/Current Level?	Yes	No	Yes, unit [mili Amps]	Same to SP Note 3
Time Range (minutes)		120 minutes	20-open	Yes, unit [minutes] Max 30 [minutes]	Different Note 4
Compliance with Voluntary Standards?		Yes: CEI EN 60601-1 CEI EN 60601-1-2 IEC 60601-1-6 CEI EN 60601-2-10 CEI EN 62304 CEI EN 62366-1 CEI EN 60601-1-11 IEC 62133	Yes: IEC 60601-2-10 IEC 60601-1-11 IEC 60601-1-6 ISO 10993-1	Yes: AAMI/ANSI ES 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-6 IEC 62304 ISO 14971 IEC 62366	Similar Note 5
Compliance with 21 CFR 898?		Yes	Yes	Yes	Same
Weight		Electrostimulator: 4.62 oz. (131g) Tablet: 10.76 oz. (305g) Receiver: 0.49 oz. (14g)	1.76 oz. (50g)	Remote: 0.24 lbs with battery Stimulation Module: 0.11 lbs per module Docking Station: 3 lbs	Different Note 4
Dimensions (in.) [W x H x D]		Electrostimulator: 3.5 x 0.81 x 3.5 (in) Tablet: 4.79x0.32 x7.56 (in) Receiver: 2.75 x 0.55 x 1.06 (in) Electrodes: 2 x 2 (in) or 2 x 4 (in) Saver protection (height): 3 (in)	1.93 x 0.64 x 3.28 (in)	Remote: 4.3 x 2.7 x 0.8 in Stimulation Module: 0.8x(2.36 x 0.8) in Docking Station tablet: 5.5x10.6x1.2 [in]	Different Note 4
Housing Materials and Construction		Electrostimulator: ABS Tablet: Plastic Receiver: PVC Electrodes: Conductive hydrogel Saver protection: Elastic	Molded PC\ABS Plastic Bayblend FR3010	N/A	Similar to PP Note 4

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Note 1

The subject and the predicate devices are substantially equivalent for "Power Source", "Method of Line Current Isolation", "Patient Leakage Current" and "Average DC current through electrodes when device is on but no pulses are being applied (μA)".

The three devices are all supplied with similar internal rechargeable Li-ion battery with no line connection, with no or negligible.

"Average DC current through electrodes when device is on but no pulses are being applied" value is not specified in the predicate devices available information, while it has a negligible value for the subject device, hence it does not impact on Its safety.

Note 2

The subject device presents differences in the functions' specifications for "Number of Output Modes" and "Number of Output Channels", with a single output mode and a single channel, compared to the multiple outputs of predicate devices. This does not raise any safety or effectiveness issue for subject device. Moreover, both the subject and the predicates can rely on their compliance with IEC 60601-1 and IEC 60601-2-10 requirements.

Note 3

For "Regulated Current or Regulated Voltage", "Automatic Overload Trip", "Automatic No-Load Trip", the subject device is equivalent to the primary predicate, while It implements the "Voltage/Current Level Indicator Display" as the secondary predicate. Hence, on this item there is no impact on safety or effectiveness for Shoulder Pacemaker.

Note 4

The subject and both the predicates have a specific "Time Range" limit, with different values. The differences in specific values do not represent any impact on safety, but they rather characterize a parameter optimized for the specific treatment. Although the "Weight", "Dimensions" and "Housing Materials and Construction" of the subject device show slight difference compared to the predicates, they all comply with IEC 60601-1 and IEC 60601-2-10 standards requirements. Hence, these differences do not raise any safety or effectiveness issue for Shoulder Pacemaker.

Note 5

The subject device has been tested according to IEC 60601-1, 60601-2, 60601-1-6, 60601-1-11, 60601-2-10 standards and meets all these standards requirements and FDA guidance requirements too.

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Device Characteristic	**Shoulder PacemakerTM (This 510(k) Application)**	**CyMedica e-vive System; CY-1000 Primary Predicate (PP)**		**Chattanooga Revolution Wireless Secondary Predicate (SP)**	**Comparison**
		NMES POST-OP	**NMES POST-STRENGTH**		
Output Specifications					
Waveform (e.g., Pulsed monophasic, biphasic)	Biphasic	Pulsed Monophasic	Pulsed Monophasic	Symmetrical Biphasic Waveform	Different
Shape (e.g., rectangular, spike, rectified sinusoidal)	Complex	Complex	Complex	Rectangular	Same as PP
Maximum Output Voltage (specify units) (+/- %)	VRMS 4.7V@ 500 Ω VRMS 9.4V@ 2 kΩ VRMS 17V@ 10 kΩ	8.5V@500Ω 15.5V@2kΩ 20.2V@10kΩ	8.4V@500Ω N/A@2 kΩ N/A @ 10 kΩ	60 V @ 500 Ω 180V @ 2 kΩ 180 V @ 10 kΩ	Similar to PP Different from SP
Maximum Output Current (specify units) (+/- %)	IRMS 9.4mA @ 500 Ω IRMS 4.7mA @2 kΩ IRMS 1.7mA @10kΩ	17.1mA@500 Ω 7.7 mA@2 kΩ 2.0 mA@10 kΩ	N/A	120 mA@500 Ω 90 mA @ 2 kΩ 18 mA @ 10 kΩ	Similar to PP Different from SP
Pulse Width (specify units)	1-200 [µs] (microseconds)	5000 µs	5000 µs	300 to 400 [µs] (microseconds)	Different
Frequency (Hz)	1 to 100 Hz	50 Hz	50 Hz	1 to 100 Hz	Same to SP Similar to PP
For interferential modes only: Beat Frequency (Hz)	N/A	N/A	N/A	N/A	Same
For multiphasic waveforms only: Symmetrical phases?	N/A	N/A	N/A	Yes	Same as PP Different from SP
For multiphasic waveforms only: Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	Stim phase: 1-200[µs] Compensation phase: 9800-999.999 [µs]	N/A	N/A	-	Different
Net Charge	0 [µC] @	342 @500Ω	336 @500Ω	0 [µC] @ 500Ω	Same as SP

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Device Characteristic	**Shoulder PacemakerTM (This 510(k) Application)**	**CyMedica e-vive System; CY-1000 Primary Predicate (PP)**		**Chattanooga Revolution Wireless Secondary Predicate (SP)**	**Comparison**
		NMES POST-OP	**NMES POST-STRENGTH**		
(µC per pulse) (If zero, state method of achieving zero net charge)	500Ω Excitation pulse fully compensated			Excitation pulse fully compensated	
Maximum Phase Charge (µC)	10 [µC] @ 500 Ω	342 @500Ω	336 @500Ω	48 [µC] @500Ω	Different
Maximum Current Density (mA/cm^2)	0.48 mA/cm2	0.66 @500Ω	0.65 @500Ω	2.1mA/cm2	Similar to PP Different from SP
Maximum Power Density (W/cm^2) (using smallest electrode conductive surface area)	0,003 W/cm2@500 Ω	0.005 @500Ω	0.006 @500Ω	0,036 W/cm2 @500Ω	Similar to PP Different from SP
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, no burst mode	150 0.087 3 0.26	50 0.23 1 0.23	N/A, no burst mode	Same as SP

Considering the output specifications, it can be noticed that:

- The subject device has a biphasic waveform with a complex shape. Primary predicate has the same shape (complex), but its waveform is limited to a single phase (pulsed monophasic). The presence of the second phase in Shoulder Pacemaker waveform allows to implement the compensation effect. The pulse compensation can eliminate any direct current component to prevent the risk of residual polarization at skin level. This waveform implementation approach is typically adopted in muscle stimulators (as in the secondary predicate, chosen for the present substantial equivalence demonstration). In fact, as for the secondary predicate device case, in the subject device the net charge is zero µC and the excitation pulse results fully compensated, so the risks of polarization are eliminated.

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- The maximum current density value is different in the subject device compared to the predicates, but its value is lower than the critical value (2mA/cm^2), as reported in the IEC 60601-2-10 standard.
- The maximum power density value depends on the dimension of electrode conductive surface area. The values are different between the devices; anyway, the subject device value is lower than the predicates ones; therefore, this is a condition of greater safety in the subject device compared to the predicates.
- The Shoulder Pacemaker has the same range of frequency of the secondary predicate.
- The Maximum Output Voltage and Maximum Output Current values are different between the devices. The primary predicate has a complex shape waveform like the subject device, so these two devices show comparable output values.
- The Maximum Phase Charge of the subject device is the lowest of the two predicates, ensuring less impact on the patient, by satisfying the technical requirements for hardware operation as well.
- The Pulse Width range of the subject device is lower than the two predicates; anyway, this range value satisfies the desired stimulation conditions.

In conclusion, the few differences in the *Basic Unit Characteristics* and *Output Specifications* between the interested devices, as shown in above reported table, do not raise any new questions of safety or effectiveness in the Shoulder Pacemaker, compared to the chosen predicates.

7 PERFORMANCE DATA

Non-clinical testing data are submitted, referenced, or relied upon, to support the demonstration of substantial equivalence of the Subject with the chosen Predicate devices.

To demonstrate the safety, the Shoulder Pacemaker was tested for electrical safety, electromagnetic compatibility, usability, and risk management requirements, according to the following standards:

- CEI EN 60601-1 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- CEI EN 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- CEI EN 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- CEI EN 60601-1-11 Medical electrical equipment 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

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- IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- CEI EN 62366-1 Medical devices — Part 1: Application of usability engineering to medical devices
- CEI EN 62304 Medical device software – Software life cycle processes
- ISO 14971 Application of risk management to medical devices

BLE module testing was conducted in accordance with the following standards:

- FCC 47 CFR PT 15 SPT B, Issued: 2013/01/28 Title 47 CFR Part 15 Subpart B: Unintentional Radiators [FCC §15.107 & FCC §15.109]
- FCC 47 CFR PT 15 SPT C, Issued:2007/10/01 Title 47 CFR Part 15 Subpart C: Intentional Radiators [FCC §15.247]

Battery testing was conducted in accordance with:

- IEC 62133-1:2017 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 1: Nickel systems
- IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

To demonstrate the Shoulder Pacemaker' effectiveness and performance substantial equivalency with the chosen predicate devices and to draft the present submission, the following FDA guidance document was used:

- FDA Final *Guidance Document for Powered Muscle Stimulator 510(k)*, issued on June 9, 1999

Electrical safety and Electromagnetic Compatibility (EMC) testing were conducted on the Shoulder Pacemaker; It complies with CEI EN 60601-1, CEI EN 60601-2-10, and CEI EN 60601-11 standards for safety and with CEI EN 60601-1-2 standard for EMC.

The device's software has been validated in accordance with the requirements set forth in the FDA *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (May 11, 2005) and according to CEI IEC 62304 Medical device software – Software life cycle processes. The software validation tests demonstrated that the software version meets its design requirements.

8 CONCLUSIONS

Based on the performance testing and the supporting documentation, it can be concluded that the Shoulder Pacemaker is as safe and effective as, and substantially equivalent to, the chosen predicate devices.