October 14, 2022

NCS Lab Srl
% Tim Marjenin
Vice-President
Mcra, LLC
803 7th St. NW
Washington, District of Columbia 20001

Re: K220994
Trade/Device Name: Shoulder PacemakerTM
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, KQX, HCC
Dated: August 23, 2022
Received: August 25, 2022

Dear Tim Marjenin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CDR Jitendra Virani, MS MBA
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220994

Device Name
Shoulder PacemakerTM

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

The device is intended for adults and adolescents age 14 and older.

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 (21 CFR 807.92)

1 GENERAL INFORMATION

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Contact Person
Matteo Mantovani
Technical Director – CEO
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Date Prepared: August 23, 2022

2 DEVICE

Trade Name	Shoulder Pacemaker™
Common/Usual Name	Muscle Stimulator
Regulation Description (Regulation Number)	Powered Muscle Stimulator (21 CFR 890.5850)
Device Class, Submission Type	Powered Muscle Stimulator Class II, 510(k)
Product Code	IPF
Additional Product Codes	KQX, HCC
Review Panel	Physical Medicine, Orthopedic, Neurology

3 PREDICATE DEVICE

	Brand Name	510(k) number	Manufacturer	Product code
Predicate				
	Shoulder Pacemaker™	K210674	NCS Lab Srl	IPF, KQX

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

The purpose of this 510(k) was to expand the indications for use to include a younger population of patients. It was originally cleared for use by adults.

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

The Indications for Use for the Shoulder Pacemaker™ device are:

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

The device is intended for adults and adolescents age 14 and older.

6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

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

- *Shoulder Pacemaker™*, which has been cleared through 510(k) application K210674.

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The Shoulder Pacemaker™ subject device is equivalent to the Shoulder Pacemaker™ (K210674). Electrical stimulation is well documented in the literature and confirmed in clinical performance as a safe and effective treatment for neuromuscular electrical stimulation (NMES). The following tables summarizes similarities and differences among the subject and the predicate devices. The comparison of the technological characteristics indicates that the differences do not raise any new questions of safety or effectiveness in the Shoulder Pacemaker compared to the chosen predicate.

Device Characteristic	**Subject device (This 510(k) Application)**	**Predicate (Shoulder Pacemaker™)**	**Comparison**
Manufacturer	NCS Lab Srl	NCS Lab Srl	Same
510(k) Number	Under present review	K210674	-
Device Name, Model	Shoulder Pacemaker	Shoulder Pacemaker	Same
Classification Regulation	890.5850 888.1500	890.5850 888.1500	Same
Product Code	IPF: Powered Muscle Stimulator KQX: Goniometer AC-powered	IPF: Powered Muscle Stimulator KQX: Goniometer AC-powered	Same
Class	II	II	Same
Primary Function	Shoulder Pacemaker is an electrotherapy device intended for neuromuscular electrical stimulation (NMES).	Shoulder Pacemaker is an electrotherapy device intended for neuromuscular electrical stimulation (NMES).	Same
Indication for Use	The Shoulder Pacemaker™ electrotherapy device is intended for neuromuscular electrical stimulation (NMES). The Indications for Use for the Shoulder Pacemaker™ device are: - Prevention or retardation of disuse atrophy; - Muscle re-education - Maintaining or increasing range of motion. The device is intended for adults and adolescents age 14 and older.	The Shoulder Pacemaker™ electrotherapy device is intended for neuromuscular electrical stimulation (NMES). The Indications for Use for the Shoulder Pacemaker™ device are: - Prevention or retardation of disuse atrophy; - Muscle re-education - Maintaining or increasing range of motion. The device is intended for adults only.	Subject device is intended for expanded age rage to include adolescents 14 and older.
<u>Basic Unit Characteristics</u>			

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Power Source(s)		Rechargeable Li-ion battery, 3.7V / 550 mAh 1.01 x 1.67 x 0.25 (in)	Rechargeable Li-ion battery, 3.7V / 550 mAh 1.01 x 1.67 x 0.25 (in)	
Method of Line Current Isolation		N/A Battery operated device	N/A Battery operated device	Same
Patient Leakage Current	**Normal condition (µA)**	N/A Battery operated device	N/A Battery operated device	Same
	Single fault condition (µA)	N/A Battery operated device	N/A Battery operated device	Same
Average DC current through electrodes when device is on but no pulses are being applied (µA)		<0.01µA	<0.01µA	Same
Number of Output Modes		1	1	Same
Number of Output Channels		1	1	Same
• **Synchronous or Alternating?**		N/A	N/A	Same
• **Method of Channel Isolation**		N/A	N/A	Same
Regulated Current or Regulated Voltage?		Regulated power	Regulated power	Same
Software/Firmware/ Microprocessor Control?		Yes	Yes	Same
Automatic Overload Trip?		No	No	Same
Automatic No-Load Trip?		No	No	Same
Automatic Shut Off?		Yes	Yes	Same
Patient Override Control?		Yes	Yes	Same
Indicator Display:	**On/Off Status?**	Yes	Yes	Same
	Low Battery?	Yes	Yes	Same
	Voltage/ Current Level?	Yes	Yes	Same
Time Range (minutes)		120 minutes	120 minutes	Same
Compliance with Voluntary Standards?		Yes: - CEI EN 60601-1 - IEC 60601-1:	Yes: - CEI EN 60601-1 - IEC 60601-1:	Same

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	2005+AMD1:2012 - CEI EN 60601-1-2 - IEC 60601-1-2:2014 - IEC 60601-1-6 - CEI EN 60601-2-10 - IEC 60601-2-10:2016 - CEI EN 62304 - CEI EN 62366-1 - CEI EN 60601-1-11 - IEC 60601-1-11:2015 - IEC 62133	2005+AMD1:2012 - CEI EN 60601-1-2 - IEC 60601-1-2:2014 - IEC 60601-1-6 - CEI EN 60601-2-10 - IEC 60601-2-10:2016 - CEI EN 62304 - CEI EN 62366-1 - CEI EN 60601-1-11 - IEC 60601-1-11:2015 IEC 62133	
Compliance with 21 CFR 898?	Yes	Yes	Same
Weight	Electrostimulator: 4.62 oz. (131g) Tablet: 10.76 oz. (305g) Receiver: 0.49 oz. (14g)	Electrostimulator: 4.62 oz. (131g) Tablet: 10.76 oz. (305g) Receiver: 0.49 oz. (14g)	Same
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)	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)	Same
Housing Materials and Construction	Electrostimulator: ABS Tablet: Plastic Receiver: PVC Electrodes: Conductive hydrogel Saver protection: Elastic	Electrostimulator: ABS Tablet: Plastic Receiver: PVC Electrodes: Conductive hydrogel Saver protection: Elastic	Same

Note 1

The subject and the predicate devices are substantially equivalent for all technical characteristics other than Indications for Use.

Note 2

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.

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Device Characteristic	**Subject device (This 510(k) Application)**	**Predicate (Shoulder PaceMaker™)**	**Comparison**
Output Specifications			
Waveform (e.g., Pulsed monophasic, biphasic)	Biphasic	Biphasic	Same
Shape (e.g., rectangular, spike, rectified sinusoidal)	Complex	Complex	Same
Maximum Output Voltage (specify units) (+/- %)	VRMS 4.7V@ 500 Ω VRMS 9.4V@ 2 kΩ VRMS 17V@ 10 kΩ	VRMS 4.7V@ 500 Ω VRMS 9.4V@ 2 kΩ VRMS 17V@ 10 kΩ	Same
Maximum Output Current (specify units) (+/- %)	IRMS 9.4mA @ 500 Ω IRMS 4.7mA @2 kΩ IRMS 1.7mA @10kΩ	IRMS 9.4mA @ 500 Ω IRMS 4.7mA @2 kΩ IRMS 1.7mA @10kΩ	Same
Pulse Width (specify units)	1-200 [µs] (microseconds)	1-200 [µs] (microseconds)	Same
Frequency (Hz)	1 to 100 Hz	1 to 100 Hz	Same
For interferential modes only: Beat Frequency (Hz)	N/A	N/A	Same
For multiphasic waveforms only: Symmetrical phases?	N/A	N/A	Same
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]	Stim phase: 1-200[µs] Compensation phase: 9800-999.999 [µs]	Same
Net Charge (µC per pulse) (If zero, state	0 [µC] @ 500Ω Excitation pulse fully compensated	0 [µC] @ 500Ω	Same

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method of achieving zero net charge)			
Maximum Phase Charge (µC)	10 [µC] @ 500 Ω	10 [µC] @ 500 Ω	Same
Maximum Current Density (mA/cm^2)	0.48 mA/cm2	0.48 mA/cm2	Same
Maximum Power Density (W/cm^2) (using smallest electrode conductive surface area)	0,003 W/cm2@500Ω	0,003 W/cm2@500Ω	Same
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	N/A, no burst mode	Same

In conclusion, the there is one difference in the *Basic Unit Characteristics* and *Output Specifications* between the interested devices, as shown in above reported tables, but it does not raise any new questions of safety or effectiveness in the Shoulder Pacemaker, compared to the chosen predicate.

7 PERFORMANCE DATA

All non-clinical, BLE module, battery, electrical safety, EMC and software testing was reviewed in K210674. No substantial changes have been made to the device since it was cleared by the FDA on August 24, 2021 that would affect prior testing results.

Non-clinical testing data are submitted, referenced, or relied upon, to support the demonstration of substantial equivalence of the Subject with the chosen Predicate device. 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 and IEC 60601-1:2005+AMD1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

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- CEI EN 60601-1-2 and 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
- CEI EN 60601-2-10 and IEC 60601-2-10:2016 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 and IEC 60601-1-11:2015 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
- 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 as well as the

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following FDA recognized standards IEC 60601-1:2005+AMD1:2012, IEC 60601-2-10:2016, IEC 60601-1-11:2015 and IEC 60601-1-2:2014.

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.

Clinical Testing and Extrapolation to Pediatric Use:

In support of expanding the eligible patient population to include individuals 14 and older, NCS has provided a discussion based on the June 2016 FDA guidance document, "Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices."

Published literature and real-world use data are provided to support extrapolation to the pediatric population. The clinical evidence, combined with comparisons of the patient, disease, and device characteristics for both the adult and pediatric sub-populations, supports the expansion of the indications for use down to age 14 via pediatric extrapolation.

8 CONCLUSIONS

Based on the performance testing and the supporting documentation, it can be concluded that the Shoulder Pacemaker is substantially equivalent to the predicate device.