DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 4, 2016

Spinal Acoustics, LLC
Albert A. Torrence
President and CEO Spinal Acoustics, LLC
640 Fourth Street
Beaver, Pennsylvania 15009

Re: K160278
Trade/Device Name: VSTAAR AdjusteR
Regulatory Class: Unclassified
Product Code: LXM
Dated: October 1, 2016
Received: October 4, 2016

Dear Albert Torrence:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160278

Device Name
VSTAAR AdjusteR

Indications for Use *(Describe)*
The VSTAAR is a mechanical device intended to be used by chiropractors, medical doctors and other licensed health care professions for the external analysis and adjustment of the human spinal column, and for soft tissue musculoskeletal mobilization.

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

510(k) Number:	K160278
Company Name:	Spinal Acoustics LLC
Company Address:	Fourth Street Professional Building 640 Fourth Street Beaver, PA 15009
Contact:	Albert Torrence, President and CEO
Phone/FAX Numbers:	(724) 513-0354 (mobile) (724) 775-5200
Email Address:	torrencelaw@comcast.net
Trade Name:	VSTAAR AdjusteR
Common/Classification Name:	Chiropractic Adjusting Instrument /Manipulator, Plunger-like Joint
Classification Regulation:	Unclassified
Device Class:	Class II
Product Code (Procode):	LXM
Preparation Date:	June 29, 2012

A. LEGALLY MARKETED PREDICATE DEVICE – as required by 807.92(a)(3)

One of the identified legally marketed predicate devices identified by the submitter is **Smart Adjuster, K962239**, submitted by Sigma Company [now known as Sigma Instruments]. A second legally marketed predicate device is **PulStarFRAS, K973914**, submitted by Sense Technology. A third predicate device is the legally marketed **Impulse IQ Adjusting Instrument, K080261**, submitted by Neuromechanical Innovations, LLC.

B. SUMMARY DEVICE DESCRIPTION – as required by 807.92(a)(4)

The VSTAAR **AdjusteR** is a mechanical device used by chiropractors, medical and other licensed health care professionals for the external

analysis and adjustment of the human spinal column, and for soft tissue and musculoskeletal mobilization.

The graphical user interface is mouse driven. All of the screens are easy to find and easy to understand. Navigating from screen to screen is quick and intuitive.

The main features of the device include:

Patient Data Screen – for patient demographic entry.

Single Evaluation test mode – to determine the articular and spinal tissue's relative compliance with a single impact on controlled preload instructions.

Lateral Evaluation – allows the user to evaluate the motion from side to side of the vertebrae, measuring the relative differences between two directions, identifying subluxation in the lateral axis.

Treatment – information from the Evaluation test mode allows the user to set a forced between 5 and 60 lbs and an impulse rate between 1 and 25 cycles per second.

Preload Bar Graph – allows the user to set a range that will be used to keep the device at a specific preload during all of the patients' treatments and assessments, typically based on body type for each patient – user feedback is provided graphically showing the pliability increase during the treating segment.

Real time Feedback – assists the user's treatment decisions. The LVDT position sensor measures depressions in the tissue made by the percussive force. The user can observe when there is a greater excursion of the LVDT denoting an increase in pliability or motion of the segment and tissue, documenting a change in the tissue consistency.

Treatment Focus – the user can focus on one region of concern at a time – cervical, thoracic or lumbar/sacral – allowing for a comparison between more like segments for bone structure.

Test "Pulse" – on segments of the spine for comparison of relative compliance of those segments. Any vertebrae that will be considered a potential problem may or may not be selected by the practitioner for an adjustment.

Impulse Analysis – measuring depth of penetration and acceleration of penetration from an impact of a consistent force and the force has been shown to be essentially constant for specific substrates in both the evaluation of our instrument. The analysis assesses a region determining areas of low compliance (Minimal Pliability) and high compliance (Relatively High pliability compared to areas of Minimal Pliability). Once areas greater than 10% from one segment to the next are identified, the instrument is then used in a percussive mode (treatment) to break up muscle tension and loosen soft or articular tissue increasing mobility of the treated segments or regions. By repeated percussion affected areas are loosened, increasing the pliability of a muscle or segmental level thus increasing an area of low compliance or minimal pliability to a relatively higher level of compliance after mechanically palpating the tissue. This decreases muscle tension through mechanical compression and by simply mobilizing the affected areas allowing for more function and ROM in a segment or muscle.

PRODUCT AND TECHNICAL SPECIFICATIONS

Control Unit:

Power	120VAC/60Hz
Single-phase	2A
Dimensions	W 16.75”x D 16.75”x H 6.7”
Weight	15 lbs
Cabinet	Brushed Aluminum & Steel

Accessories:

Display	PL 1900 LCD monitor or AOC e1649Fwu USB LCD monitor
Applicator	Single Tip/Dual Tip Applicators

Adjustment Device:

Dimension	Diameter 2.5” x Length 8.75”
Weight	1.88 lbs
Cover	Polished Aluminum
Cord	8 ft

Operating Conditions:

Temperature	+18°C - +30°C
Humidity	30% - 75%
Atmospheric Pressure	500 - 1060 hPa

Shipping and Storage Conditions:

Temperature..... 30% - 75%
Humidity ..... 30% - 75%
Atmospheric Pressure ..... 500 - 1060 hPa

Operating System Software
Microsoft Windows XP and Windows 7

Application Software - Designed with National Instruments' LabView development software

Provides preloaded settings	user selects of 1 – 60 settings
Feedback	preload feedback provided
Force setting	user definable default
Pulses	multiple pulses provided
Pulse rate	user selects from 1 to 25 Hz
User interface	touch screen or mouse driven

C. INTENDED USE - as required by 807.92(a)(5)

The **VSTAAR AdjusteR** device is a tool designed by Chiropractors (DC), medical doctors (M.D. and D.O.), Physical Therapists (PT), Physicians Assistant (PA), Nurse Practitioner (NP), engineers and researchers to analyze and administer soft tissue, articular, spinal and extremity manipulations, including adjustment, and mobilization.

The graphical user interface is mouse driven. All of the screens are easy to find and easy to understand. Navigating from screen to screen is quick and intuitive.

D. INDICATIONS FOR USE - as required by 807.92(a)(5)

The VSTAAR is a mechanical device used by chiropractors, medical and other licensed health care professionals for the external analysis and adjustment of the human spinal column, and for soft tissue and musculoskeletal mobilization.

E. TECHNOLOGICAL CHARACTERISTICS SUMMARY – as required by 807.92(a)(6)

Like the predicate devices, the **VSTAAR AdjusteR** device operates on 120v 50/60 Hz power and is designed for a typical professional medical clinic environment. Within that environment, the VSTAAR device, like its predicates, is easily transported.

Like the predicate devices, the **VSTAAR AdjusteR** operates within a computer hardware/computer operating system/submitter developed application software environment.

The **VSTAAR AdjusteR** device, like its predicates, delivers a light mechanical impulse through the hand held treatment device with user selected force, pulse rate The **VSTAAR AdjusteR** device, like its predicates, has more than one tip for the adjusting or hand held treatment device. Like the predicates, the **VSTAAR AdjusteR** device has a sensor within the adjusting or hand held treatment device. Like the predicates, the **VSTAAR AdjusteR** device provides the professional user with an electromagnetic coil, user definable default settings and pulse rate settings.

Like the predicate devices, the **VSTAAR AdjusteR** device provides the user with a software interface for patient information input, operational setting selections, and storage of system generated data. Like the predicates, there is a choice of preload settings for the **VSTAAR AdjusteR** device. The **VSTAAR AdjusteR** device, like the predicates, provides multiple pulses and pulse rates.

Unlike some of the predicate devices, the **VSTAAR AdjusteR** device provides "preload feedback" to show the professional user if/how much the preload changes during treatment.

The submitted **VSTAAR AdjusteR** device has the same technological characteristics as the predicate devices. The **Substantial Equivalence Table** provides a detailed COMPARISON MATRIX of the submitted device and the identified predicate devices.

PRODUCT COMPARISON TABLE

510(k) #	Subject Device (K122038	Predicate Device (K962239)	Predicate Device (K973914	Predicate Device (K080261)	Justification
Device Name	VSTAAR AdjusteR	Smart Adjuster	PulStarFras	Impulse IQ Adjusting Instrument	N/A
IFU	The VSTAAR AdjusteR is a mechanical device intended to be used by chiropractors, medical doctors and other licensed health care professions for the external analysis and adjustment of the human spinal column, and for soft tissue musculoskeletal mobilization.	The smart adjuster is intended to be used to do both analysis and adjustments to the human spinal column in accordance with standard chiropractic procedures. These procedures include the location and return to normal compliance of joint fixations and adhesions.	Indications for use of the pulstarfras include: musculoskeletal pain due to joint subluxation, restricted joint mobility, myofacial spasm, ligamentous strain.	The impluse IQ adjusting instrument is intended for chiropractic adjustment, mobilization, or manipulation of the musculoskeletal joints of the spine and/or extremities or for soft-tissue musculoskeletal mobilization by a licensed health care professional only. For external use only	Similar
Power source	AC Powered	AC Powered	AC Powered	AC Powered	Identical
Method of delivering thrust force	Spring	Solenoid	Solenoid	Solenoid	Different but does not adversely affect the safety and effectiveness of the subject device
Force settings	5 – 60lbs	10 - 35lbs	10 - 35lbs	22.5 - 90lbs	Similar

Applicator tip velocity	5.65 ft/s	Unknown	3.0 ft/s	6.29 ft/s	Similar
Pulse Rate	1 - 12 Hz	Unknown	2 -12 Hz	4 - 12 Hz	Similar
Range of displacement (inches)	Max 0.210	Max 0.260	Max 0.12	Max 0.145	Similar
Duration of Force	2-4 ms	Unknown	Unknown	2-4 ms	Similar
Patient-contacting material	60 Durometer Silicone	Rubber Tipped Probe	Unknown	Rubber contact end	Different but does not adversely affect the safety and effectiveness of the subject device
Sensor within handheld device	Linear Variable Differential Transformer (LVDT)	Force sensor	Force sensor	Accelerometer	Different but does not adversely affect the safety and effectiveness of the subject device
Max count of impulses	60	Unknown	1 - 200	12	Similar

F. NON-CLINICAL PERFORMANCE DATA TESTING AND REVIEW - as required by 807.92(b)(1)

Non-Clinical Testing

The submitted **VSTAAR AdjusteR** device has undergone significant verification and validation testing. Validation testing included verification testing of major components of the device to document conformance to device specifications and validation testing to confirm the device met its intended uses and requirements.

The performance data records documents that the **VSTAAR AdjusteR** device met its stated requirements and design specifications as intended.

Electrical Safety Testing – Electromagnetic Compatibility & Electrical Safety

The submitted device has been tested in conformance with **IEC 60601-1 / EN 60601-1 Medical electrical equipment — Part 1: General requirements for safety** (IEC 60601-1:1988 + A1:1991 + A2:1995), by **Intertek, Twinsburg, OH**, and **IEC 60601-1-2 Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests**, by a **Keystone Compliance**, New Castle, PA, both qualified testing laboratories.

SUMMARY STATEMENT

Spinal Acoustics, LLC believes the **VSTAAR AdjusteR** device's summary of non-clinical testing and electrical safety testing data further documents the submitter's claim of substantial equivalence.

CONCLUSION

The performance testing and testing data document that the submitted **VSTAAR AdjusteR** device is substantially equivalent to the Sigma Company's [now known as Sigma Instruments] predicate Smart Adjuster, K962239, Sense Technology Inc.'s predicate PulseStarFRAS, K973914, and Neuromechanical Innovations, LLC's predicate Impulse IQ Adjusting Instrument, K080281.