June 26, 2018

Spinalight, Inc
Stanford Pierce
President
6721 23rd Street North
St. Petersburg, Florida 33702

Re: K172536
Trade/Device Name: Atlas Percussion Adjusting Instrument, Model C-1000
Regulatory Class: Unclassified
Product Code: LXM
Dated: May 24, 2018
Received: May 29, 2018

Dear Stanford Pierce:

This letter corrects our substantially equivalent letter of June 20, 2018.

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William J. Heetderks -S
2018.06.26 12:41:48 -04'00'

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)*
K172536

Device Name
Atlas Percussion Adjusting Instrument Model C-1000

Indications for Use *(Describe)*

The Spinalight Atlas Percussion Instrument is to be used by a licensed Chiropractor to assist in making a Chiropractic adjustment to the atlas vertebrae. This adjustment is indicated when the doctor believes this bone to be out of alignment.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY K172536
(as required by 807.92)

I. SUBMITTER

Spinalight, Inc
6721 23rd Street North
St. Petersburg, FL 33702
Contact Person: Dr. G. Stanford Pierce
Email: award@ajwtech.com
Date Prepared: 25 June 2018

II. DEVICE

Name of Device: Atlas Percussion Adjusting Instrument, Model C-1000
Common or Usual Name: Manipulator, Plunger-Like Joint
Classification Name: Manipulator, Plunger-Like Joint
Device Panel: Physical Medicine
Regulatory Class: Unclassified
Unclassified Reason: Pre-Amendment
Product Code: LXM
Regulation Number: None

III. PREDICATE DEVICE

Device: The Atlas Adjusting Instrument, Model 8000
Manufacturer: Spinalight, Inc
510(k) Reg. No: K946258
This predicate device has not been subject to a design-related recall.
Regulatory Class: Unclassified
Product Code: LXM
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Percussion Adjusting Instrument is comprised of a Chiropractic Adjusting Table and a support system with a percussion device, which a Chiropractor positions over his patient to deliver an adjustment to the Atlas Vertebra (C-1). After the doctor positions the patient on the table, he aligns the instrument head so that the stationary stylus is positioned to the Atlas on predetermined vectors. Once this is completed the Chiropractor activates a solenoid contained within the adjusting head which strikes the proximal end of the stationary stylus generating a percussion wave through the stylus into the transverse process of the Atlas Vertebra. The objective is to produce a movement of the Atlas toward its proper alignment under the skull. Any time the

patient is being positioned on the table or headpiece the percussion head is placed in the "Safe to Move" position.

V. INDICATIONS FOR USE

The Spinalight Atlas Percussion Instrument is to be used by a licensed Chiropractor to assist in making a Chiropractic adjustment to the atlas vertebrae. This adjustment is indicated when the doctor believes this bone to be out of alignment.

VI. CONTRA-INDICATIONS

Do not use on:

1. Fractures
2. Bones incapable of bearing body weight due to pathological processes
3. Osteoporosis
4. Soft tissue including:
    a. Eyeball
    b. Testicles
    c. Mammary glands
    d. Ovaries
    e. Auditory Canal

Contra-indications for the self-adjustment itself are:
The adjustment should not be attempted with a patient who has had neck or cervical or spinal surgery, or has infected or inflamed areas or open wounds near the cervical spine. Adequate precautions should be taken in cases of persons suspected or diagnosed with epilepsy.

VII. DEVICE MODIFICATIONS

The Atlas Percussion Adjusting Instrument Model C-1000 is an update of the Atlas Adjusting Instrument Model 8000. The differences are the following:

1. Table Shoulder Section from Fixed to Movable
   Proper placement of the patient in the side posture position on the adjusting table produce mild biomechanical influences on the upper cervical articulations to affect a better outcome in the re-alignment of the atlas vertebra. The predicate device required the doctor to manually lift and reposition the patient's shoulders to get them in the proper position. The moveable shoulder section on the New Device activated by a 4-way joy stick, enables the doctor to make precise positioning changes of the patient. An electric drive motor was added to enable the clinician to adjust the shoulder section by use of the added joy stick. This is for ease of patient positioning and has no impact on safety or effectiveness.

2. Percussion Adjusting Head from Variable Wave Setting to Single Wave Setting
   The New Device eliminates the un-used, variable settings, and uses one percussion setting.

3. Percussion Head Actuator from Foot Pedal Activation to Push Button Activation
   The percussion head actuator on the predicate device was initiated by a foot pedal on the floor. The New Device has replaced the foot pedal with a push button mounted on the percussion head. This assists the doctor in maintaining his focus on the patient/instrument relationship during the adjustment of the atlas vertebra. The push button control also may help to reduce the possibility of the clinician inadvertently stepping on the foot pedal.

4. Head Piece Tilt Adjustment from Push Button Control to Toggle Switch Control
   This action of setting the head piece tilt angle is important in stabilizing the patients head before and during the percussion atlas adjustment. The predicate device utilized a manual, screw-type mechanism for this purpose. The New Device provides a motor driven tilt mechanism which is activated by a self-centering toggle switch. This may help the doctor to simultaneously observe the patient and the tilt positioning of the head piece while it is being adjusted. An electric drive motor was added to enable the clinician to adjust the head piece tilt section by use of the added self-centering toggle switch for patient positioning, which has no impact on safety or effectiveness.

5. Table Top Pad from 1" Thick to 2.5" thick
   Since the establishment of the original 510K for the predicate device, there has been substantial improvement in the quality and durability of foam rubber padding. The New Device will incorporate a 2.5-inch marine foam padding which affords greater comfort to the patient without compromising the efficiency of the device in its intended purpose. The pad change was only for patient comfort and is the most standard table top pad in use for chiropractic tables currently.

6. Vertical Table Lift
   The original 510K predicate device was built on a 4-legged, stationary table base. The New Device incorporates a lift mechanism which can vary the table top height from approximately 26 inches to 35 inches. This is most beneficial for wheelchair users as well as those with ambulatory difficulties. This modification is solely for patient accessibility and has no influence on the purpose nor the effectiveness of the percussion adjusting device. This is now a standard chiropractic table as the vertical lift has become a normal and not custom modification.

VIII. COMPARISON OF TECHNOLIGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table lists the technological characteristics for the new device vs the predicate device.

Characteristic	Predicate Device K946258	New Device (C-1000)
Indications for Use	The Spinalight Atlas Percussion Instrument is to be used by a licensed Chiropractor to assist in making a Chiropractic adjustment to the atlas vertebrae. This adjustment is indicated when the doctor believes this bone to be out of alignment.	The Spinalight Atlas Percussion Instrument is to be used by a licensed Chiropractor to assist in making a Chiropractic adjustment to the atlas vertebrae. This adjustment is indicated when the doctor believes this bone to be out of alignment.
Table width	24”	24”
System overall length	Approx. 100”	Approx. 100”
System weight	Approx. 300 lbs.	Approx. 300 lbs.
Table Shoulder Section	Fixed	Movable
Floor and Head Protractor for positioning	Yes	Yes
Fixed Stylus	Yes	Yes
Percussion Adjusting Head	Variable Percussion Wave Settings	Fixed Percussion Wave Setting
Percussion Actuator	Activated by Foot Pedal	Activated by Push Button
Percussion Head Position Lock	Yes	Yes
Power	115 VAC	115 VAC
Device Vertical Adjustment	Electric vertical lift column	Electric vertical lift column
Head Piece Vertical Adjustment	Toggle Switch Control	Toggle Switch Control
Head Piece Tilt Adjustment	Manual operated screw control	Motorized
Table Pad	Approx. 1” thick	Approx. 2.5” thick
Table Top	Vinyl covered	Vinyl covered
Foot Rest Extender	Yes	Yes
Vertical table lift	None	Yes

The differences in characteristics between the subject and predicate device were implemented for convenience and comfort purposes. The differences do not change how the device is used nor do they adversely impact the safety or effectiveness of the device.

IX. PERFORMANCE DATA

Summary of Testing:
The Atlas Percussion Adjustment Instrument C-1000 was tested and compared to the predicate device in a number of areas. The changes made in the Atlas Percussion Adjustment Instrument C1000 do not affect the safety of the device. This conclusion is based on the following verification/performance tests having been completed:

- Electromagnetic Immunity Testing of the Atlas C-1000 to radiated Radio-Frequency (RF) Emissions from RF transmitters
- Testing to measure and calculate the acoustic pressure transmitted from the stylus of the Atlas C-1000
- Testing to measure the force imparted by the solenoid to the stylus of the Atlas C-1000
- Patient positioning and adjustment tests.
- EMC and Electrical Safety Testing

In addition, a Risk analysis was prepared to include consideration of the above changes.

Based on the results of the performance testing it has been determined that the Atlas Percussion Adjusting Instrument is substantially equivalent to the predicate.

X. CONCLUSIONS

By virtue of its intended use and physical and technological characteristics, the Atlas Percussion Adjustment Instrument C-1000 is substantially equivalent to the Spinalight Predicate device that has been cleared for marketing in the United States. The performance data shows that the Atlas Percussion Adjustment Instrument C-1000 is as safe and effective as the predicate device.