U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Spinetronics, LLC 7/25/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration

Florida District
555 Winderley Place, Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
FLA-11-32

July 25, 2011

Dr. David B. Bass
President
Spinetronics, LLC
10251 West Sample Road
Coral Springs, Florida 33065-3928

Dear Mr. Bass:

During an inspection of your firm located in Coral Springs, Florida on February 28, 2011, through March 1, 2011, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the Antalgic-Trak. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), this product is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body.

This inspection revealed that this device is adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

Violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a)(1).

For example: You do not have design control procedures. You also have no documentation of design validation or design change controls for the Antalgic-Trak, including no documentation of risk analysis or structural **(b)(4)** testing of the embedded software.

2. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d).

For example: You have no documented finished device acceptance activities procedure and no documentation of finished device acceptance activities for the Antalgic-Trak.

3. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50.

For example: You do not have purchasing control procedures. You also indicated that you are not aware of the quality system activities performed at your contract manufacturer, **(b)(4)**

4. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a).

For example: You do not have nonconforming product procedures.

5. Failure to establish and maintain procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100(a).

For example: You do not have Corrective and Preventive Action (CAPA) procedures.

6. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a).

For example: You do not have complaint handling procedures. Additionally, though you maintain a complaint file, it does not include all of the complaints you have received and complaints dated 3/18/2008, 5/22/2008, 9/23/2008, 10/30/2008, 12/3/2008, and 1/12/2009, do not include the required documentation of an investigation or rationale and approval for not performing an investigation.

7. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22.

For example: You do not have quality audit procedures and do not conduct quality audits.

Our inspection also revealed that your device is misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting (MDR) regulation. Significant violations include, but are not limited to, the following:

Failure to develop, maintain, and implement written Medical Device Reporting (MDR) procedures, as required by 21 CFR 803.17.

For example: You do not have any MDR procedures.

We received a response from you, dated March 5, 2011, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations, that was issued to you. We reviewed your response and conclude that it is not adequate. While your response acknowledges the observations, it fails to address them. The response merely states that your firm has "begun the process to comply" without providing any information on any corrective actions with respect to the observations.

The Office of Compliance (OC) in the Center for Devices and Radiological Health (CDRH) also reviewed your brochure "What is the Antalgic-Trak?," the Operating Manual for the Antalgic-Trak and your website www.spinetronics.com. A review of these materials, your website, and our records revealed that you are marketing the Antalgic-Trak without marketing clearance or approval, in violation of the Act. Specifically, the Antalgic-Trakis adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The device is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b).

Your device is not covered by the existing 510(k), K042482, because your brochure, Operating Manual and website include claims for Antalgic-Trak that were not cleared under K042482, and represent a major change or modification in the intended use of the device under 21 CFR 807.81(a)(3)(ii). Examples of such claims include, but are not limited to, the following:

1. Page 5 of the Operating Manual refers to the Antalgic-Trak as "the World's first range-of-motion decompression chair," "an evolutionary leap in decompression therapy," and "an improved and more controlled way to perform both cervical and lumbar decompression." The brochure also describes Antalgic-Trak as providing "spinal decompression." In a letter from Mark Melkerson dated October 26, 2007, you were informed that if you use the term "decompression" in labeling for the Antalgic-Trak, "you should qualify this statement each time it is used by defining decompression as unloading due to distraction and positioning." Neither the Operating Manual nor the brochure defines decompression as "unloading due to distraction and positioning."

2. Your brochure refers to Antalgic-Trak as providing "Articulating Non-Surgical Spinal Decompression with ROM," and states "it is the only *ROM articulating decompression system in the world," "Cervical (neck) and lumbar (low back) spine and disc conditions are effectively treated on the Antalgic-Trak. The exclusive articulating features of Antalgic-Trak provide a gentle, soothing and effective treatment that patients and doctors appreciate," and "With articulating decompression the patient can be placed in the posture that best suits their condition. It is a multi-directional, multi-postural unlimited therapy." These statements identify rotational movement capability of the device as a distinct treatment modality, rather than as a precursor adjustment to the application of linear traction for the purpose of patient comfort.

3. Your brochure also states that "Antalgic-Trak's posturing features provide new treatment options for arthritis, scoliosis, stenosis, spondylosis, segment subluxation, disc bulges, herniations, and pinched nerves." This statement represents the device as providing treatment of these diseases or conditions rather than alleviating the pain associated with these diseases or conditions, and some of these diseases or conditions are not included in the indications for use cleared under K042482.

4. Your website www.spinetronics.com refers to the Antalgic-Trak as a "spinal elongation system." While improvement of intervertebral spacing might conceivably be associated with spinal elongation, the terminology "spinal elongation" in this context suggests a more global, quantitatively measurable effect than improvement in intervertebral spacing.

The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at http://www.fda.gov/cdrh/devadvice/3122.html[1]. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject device have been corrected.

Please notify this office in writing within fifteen (15) business days from the date you receive this letter of the specific steps you have taken to correct the noted violations, as well as an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions you have taken. If your planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of these activities. If corrections and/or corrective actions cannot be completed within 15 business days, state the reason for the delay and the time within which these activities will be completed. Your response should be comprehensive and address all violations included in this letter.

Your response should be sent to:

Salvatore N. Randazzo, Compliance Officer
555 Winderley Place, Suite 200
Maitland, Florida, 32751

Refer to the Unique **Identification Number 183812** when replying. If you have any questions about the content of this letter please contact: Salvatore N. Randazzo at (407) 475-4712.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. You should

investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely,
/S/
Edwin Ramos
Acting Director, Florida District

Links on this page:

1. http://www.fda.gov/cdrh/devadvice/3122.html