U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Medicepts, Inc. 1/25/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
FLA-11-13
January 25, 2011

John R. Santasiero, President
Medicepts, Inc.
2590 SE Willoughby Blvd
Stuart, Florida 34994

Dear Mr. Santasiero:

During an inspection of your firm located in Stuart, Florida on July 21, 2010 through July 23, 2010, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the Spine Six Biomotion Spinal System. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that the Spine Six Biomotion Spinal System is adulterated under section 501(t)(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). Specifically, you are marketing the device with claims for cervical or lumbar pain, herniated discs, disc bulges, radiculopathy, disc protrusions, etc. which exceeds the limitations of 21 CFR 890.9(a) for devices classified under 21 CFR 890.5380 as Powered Exercise Equipment Furthermore, the combination of available motions makes the device significantly different in technology from other powered exercise devices and thus would also exceed the limitation under 21 CFR 890.9(b) in that it operates using a different fundamentally scientific technology than a legally marketed device in that generic type of device. 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 C.F.R. 807.81(b). 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.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

In addition, FDA has noted nonconformances with the following Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at 21 CFR Part 820. These nonconformities include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures for validating the device design, as required by 21 CFR 820.30(g).

For example, you have no documentation of "white box" testing of the embedded device software for the Spine Six device as required by your firm's design control procedure.

2. Failure to establish and maintain adequate procedures for verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4).

For example, your CAPA procedures QP 852 "Corrective Action" Rev D and QP 853 "Preventive Action" Rev C do not contain any requirements for verifying and/or validating CAPA to ensure that such action is effective and does not adversely affect the finished device.

3. Failure to establish and maintain adequate 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:

a. You have no documentation of supplier audits or Certificates of Compliance for the p.c. board assembly supplie **(b)(4)** as required by your procedure AP-740 "Purchasing" Rev D.

b. You have not evaluated the base welder **(b)(4)** to ensure that the welding process has been validated with regard to weld strength.

4. Failure to establish and maintain adequate procedures for verifying the device design, as required by 21 CFR 820.30(f).

For example, documentation of design verification testing (drop/load testing) at a test facility was not available.

In addition, FDA has noted nonconformances with the following Medical Device Reporting requirements found at 21 CFR 803. These nonconformities include, but are not limited to, the following:

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

We have reviewed your response dated 8/12/2010 and have concluded that it is inadequate because though you provide QP-nnn "Medical Device Reporting" Draft to address how you will handle Medical Device Reporting requirements, you indicate that the procedure will not be finalized until a full Quality System review of the site is completed. Please provide the final, approved procedure and documentation of its implementation.

A follow up inspection will be required to assure that corrections are adequate.

Your response should be sent to: Winston R. Alejo, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have any questions about the content of this letter please contact: Mr. Alejo at (407) 475-4731.

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 assurance systems. Yo 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/
Emma R. Singleton
Director, Florida District

Links on this page:

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