Signal Medical Corporation 12/15/14

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
Detroit Dlstnct
300 River Place
Suite 5900
Detroit, Ml 48207
Telephone: 313-393-8100
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WARNING LETTER
2015-DET-03

December 15, 2014

VIA UPS

Louis A. Serafin, Jr., MD
President/Owner
Signal Medical Corporation
400 Pyramid Drive
Marysville, Ml 48040-2463

Dear Dr. Serafin:

During an inspection of your firm located in Marysville, Michigan on July 31, 2014 through August 11, 2014, investigators from the United States Food and Drug Administration (FDA) determined that your firm is a manufacturer of Class II MicroSeal Total Hip Acetabular Systems. 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 to affect the structure or any function of the body.

The MicroSeal Total Hip Acetabular System is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does 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 under section 520(g) of the Act, 21 U.S.C. § 360j(g) for the device as described and marketed. Specifically, the MicroSeal Total Hip Acetabular System includes a “hood feature” integrated with a liner that was not cleared in K955271 and K971718. The liners are identified as MicroSeal “Anatomic” (10˚ and 20˚ hood angle) liner and the MicroSeal “Stable” liner. There are also additional sizes of the MicroSeal Acetabular Liners offered for sale since the initial submission was cleared. The inner diameter sizes of the liner offered in the submission was 22mm, 26mm and 28mm. Currently your firm also manufactures liners with an inner diameter of 32mm and **(b)(4)**mm.

In addition, the MicroSeal Total Hip Acetabular System is misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm introduced into interstate commerce for commercial distribution the device with major changes and/or modifications to cleared 510(k), K955271 and K971718, and did not notify the agency of its intent to introduce the device into commercial distribution, and without the submission of a new premarket notification to FDA, as required by section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR 807.81(a)(3)(i). Specifically, your firm changed the shell and liner for the MicroSeal Total Hip Acetabular System cleared in K955271 and K971718.

For a device requiring premarket approval, the notification required by section 510(k) is deemed satisfied when a PMA is pending before the agency as defined by 21 CFR 807.81(b). The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/defau The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

We received a response from Ms. Melinda Finnie, Quality Manager (Interim), dated August 27, 2014, concerning our investigators observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations that was issued to your firm. During the close of the inspection, the investigators discussed the observed device design changes to the MicroSeal Total Hip Acetabular System, a 510(k) cleared device. The 510(k) changes as described above were not covered in your response letter.

Your firm 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 FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of 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 business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to: Catherine V. Quinlan, Compliance Officer, Food and Drug Administration at 300 River Place, Suite 5900, Detroit, MI 48207. If you have any questions about the contents of this letter, please contact Ms. Quinlan at (313)393-8153.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely,
/S/
Art O. Czabaniuk
District Director
Detroit District Office

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