GPC Medical Ltd. 10/20/17

U.S. FOOD & DRUG ADMINISTRATION

10903 New Hampshire Avenue
Silver Spring, MD 20993

WARNING LETTER

VIA UNITED PARCEL SERVICE

October 20, 2017

Mr. Vikas Narang
Director
GPC Medical Limited
M Block, DDA LSC, Vikas Puri,
New Delhi, India 110018

Dear Mr. Narang

During an inspection of your firm located in New Delhi, India on June 19, 2017 through June 22, 2017, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures GPC Bone Plates, GPC Bone Screws, GPC Intramedullary Nailing Systems, and GPC Posterior, Non-Cervical Pedicle Screw 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 to affect the structure or function of the body.

This inspection revealed that these devices are 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, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

We received a response from you dated August 1, 2017, concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, which was issued to your firm. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to ensure that when the results of a process cannot be fully verified by subsequent inspection and test that the process shall be validated with a high degree of assurance and approved according to established procedure, as required by 21 CFR 820.75(a).

For example, your firm's process validations under **(b)(4)** which include: **(b)(4)** Validation dated January 1, 2017, **(b)(4)** Validation dated January 5, 2017, **(b)(4)** dated June 1, 2017, and **(b)(4)** dated January 2, 2017 are inadequate. These validations do not include: final operational parameters of the equipment being validated, justification of product selection (e.g. most challenging to clean), sampling acceptance criterion, or verification of cleaning effectiveness.

Furthermore, the procedures for **(b)(4)** and **(b)(4)** include specifications for processing parameters, and batch sizes outside the scope of the validation performed.

We reviewed your firm's response and conclude that it is not adequate. The response indicates that corrections will be performed, but does not provide a plan, or documentation supporting that the correction has been performed.

2. Procedures for finished device acceptance have not been adequately established as is required by 21 CFR 820.80(d).

Specifically, your firm has not documented finished device sampling procedures adequately. The finished product testing Plan **(b)(4)** and the DHR indicates 100% Inspection for dimensional acceptance. However, the finished product testing report lists measurements for 1 to 5 samples with no documented justification for deviating from 100% inspection.

We reviewed your firm's response and conclude that it is not adequate. The response indicates that corrections will be performed, but does not provide a plan, or

documentation supporting that the correction has been performed.

3. Procedures to control labeling activities have not been adequately established as is required by 21 CFR 820.120.

Specifically, your Device History Records do not contain label accountability, nor is a copy of each size label within a batch maintained, e.g., Batch **(b)(4)** contains **(b)(4)** pieces with **(b)(4)** different lengths. The DHR only contains a copy of the label for one size in the batch.

We reviewed your firm's response and conclude that it is not adequate. The response indicates that corrections will be performed, but does not provide a plan, or documentation supporting that the correction has been performed.

4. Failure to establish and maintain procedures to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record as is required per 21 CFR 820.184

For example the Device History Record for the batch **(b)(4)** of the Cortical Screw does not include documentation of completion of **(b)(4)** during the manufacture of components.

This observation was not included in the FDA form 483. This item was not addressed in your responses to other observations.

U.S. 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. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected.

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, including 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 action (which must address systemic problems) 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. Please provide a translation of documentation not in English to facilitate our review. We will notify you regarding the adequacy of your firm's response**(s)** and the need to re-inspect your firm's facility to verify that the appropriate corrections and/or corrective

actions have been made.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Inspections Support Branch, White Oak Building 66, Rm 3540, 10903 New Hampshire Ave., Silver Spring, MD 20993. **Refer to CMS case #536145 when replying.** If you have any questions about the contents of this letter, please contact: **Matthew Krueger** at **301-796-5585.**

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 yours,
/S/
CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health

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More in 2017

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Contact FDA