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Trimed Inc 6/30/16

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Department of Health and Human Services

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WARNING LETTER

UNITED PARCEL SERVICE
SIGNATURE REQUIRED

June 30, 2016

WL # 35-16
Mr. David H. Medoff, Director
TriMed, Incorporated
27533 Avenue Hopkins
Santa Clarita, California 91355

Dear Mr. Medoff:

During an inspection of TriMed, Inc., located in Santa Clarita, California, conducted from March 7 through March 18, 2016, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures implantable bone fixation systems including plates, screws, nails, and wires intended to treat bone fractures of extremities, and instruments and drills used to implant these products during surgeries. 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.

This inspection revealed that your 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.

Our investigator issued the Form FDA-483, List of Inspectional Observations, to you at the conclusion of the inspection on March 18, 2016. We received a response, dated April 7, 2016, from Michael Capellan, QA/RA Manager, concerning our investigator’s observations noted on the Form FDA 483 that 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 review, evaluate and investigate complaints involving the possible failure of a device, labeling and packaging to meet any of its specifications where necessary, as required by 21 CFR 820.198(c).

For example, your firm maintains an Error Log for Return Good Authorizations (RGAs) that references failures of your devices’ labeling and packaging to meet specifications. Examples are the following RGA Numbers: 0915-94, 0915-48, 0216-480, 0216-431, 0216-432, 0216-434, 0216-172, 0116-315, 0116-296, 0116-279, 0116-215, 0116-180, 0116-42, 0116-45, and 1215-354. These were not documented as complaints, and were not investigated. Additionally, your firm found that 17 Perimeter Bone Plates, Part #WHV-4, had oversized threaded holes, which could allow the non-locking screws to go through the plate. There was at least one instance where your firm received communication that this occurred in a clinical setting, and your firm did initiate a complaint file for this event.

We reviewed your response, dated April 7, 2016 and find it is not adequate. You have not completed the corrective actions referenced in this response, nor have you provided a timeline for the completion of these activities. Additionally, in your response to FDA-483 observation 9, you stated that you would initiate a complaint file for MRB #0121, which referenced the oversized threaded holes in your Perimeter Bone Plates, Part #WHV-4; however you did not demonstrate you had initiated this corrective action.

2) Failure to conduct a complete risk analysis, as required by 21 CFR 820.30(g)

For example, the failure mode of non-locking screws passing through the hole of bone plates during surgeries has not been documented in the risk analysis for your Supracondylar Elbow Implant System.

We reviewed your response, dated April 7, 2016 and find it is not adequate. In this response, Mr. Capellan stated that risk analysis for all bone plates would be updated to address the possibility of screws, locking and non-locking, passing through the hole of the plate. Your firm has not completed this corrective action, nor have you provided a timeline for the completion of this activity.

3) Failure to adequately establish procedures for corrective and preventive action, as required by 21 CFR 820.100(a).

For example, your CAPA procedures, Document #QOP8502, Revision D, dated 05/16/12, do not include a requirement to analyze sources of quality data such as complaints documented in your Error Log, non-conformances documented in your Material Review Board Log, and returned products documented in your Returned Goods Authorization Log to identify existing and potential causes of nonconforming product, or other quality problems.

In addition, CAPA #0293 was initiated on 09/29/15 to address complaints of non-locking SMTP-10 screws that were passing through the hole of the SMTP-10 plate. The CAPA is referenced as implemented on 10/2/15 and effective on 2/9/16; however, there is no documentation to demonstrate the corrective action of revising the dimension of the screw hole was effective. Furthermore, the “Corrective Action (Plan)” references that other bone plates using the same threaded screw hole may be affected by the same issue, but CAPA #0293 does not refer to the products affected, nor is there documentation to show that effective corrective actions have been implemented for all products affected.

We reviewed your response, dated April 7, 2016 and find it is not adequate. This response references your firm will upgrade QOP8502 to include the requirement to analyze all sources of quality data, but did not reference which specific sources will be included, nor did you provide a time line for these corrections. You stated that a verification of effectiveness for CAPA #0293 will be created, as well as documentation to show effective corrective actions have been implemented for all affected products; however, you have not completed these activities, nor have you provided a timeline for their completion.

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

For example, your Control of Nonconforming Products procedure, Document #QOP8301, Revision B, does not require non-conformances to be evaluated to determine if an investigation is needed, and does not require the documentation of any investigation conducted. Material Review Board-Rework records, noted as MRB numbers 0107, 0108, 0109, 0110, 0113, 0114, 0115, 0116, 0117, 0118, 0120, 0121, 0123, 0124, 0125, 0126, and 0127 reference reports of non-conformances that did not include documentation that they were evaluated to determine whether an investigation was needed. If any investigations were performed, the investigations were not documented.

We reviewed your response, dated April 7, 2016 and find it is not adequate. This response references your firm will review and revise your procedure and your process for non-conforming products to conform with FDA regulations, and that MRB files will be reevaluated to determine if documentation of whether additional investigation will be required. You stated a product complaint record will be initiated for MRB #121. You have not completed these activities, nor have you provided a timeline for their completion.

5) Failure to adequately establish procedures for device history records, as required by 21 CFR 820.80(d).

For example, finished products shipped to a customer under Invoice **(b)(4)** did not include records that demonstrated the activities required in the device master record for your Wrist Fixation System, your Radiocarpal Fusion System, and your Ulnar Osteotomy System were completed. We reviewed your response, dated April 7, 2016 and find it is not adequate. This response references your firm will review and revise your QOP for device history records to meet FDA requirements. You have not completed these activities, nor have you provided a timeline for their completion.

6) Failure to submit a report to FDA no later than 30 calendar days after the day that your firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that it markets may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a)(1).

Based on the information included for Complaint #027, your firm became aware on February 19, 2015, of an event that associates the breakage of the implanted fixation plate to the patient necessitating surgery to remove the broken device. Your firm has not submitted an MDR for the referenced event.

Your response dated April 7, 2016, is not adequate. Your firm has not yet submitted an MDR for the referenced Complaint #027 and there is no evidence that it has implemented corrective actions that will allow your firm to meet the required reportability timeframes for the future submission of MDR reportable events.

7) Failure to submit a report to FDA no later than 30 calendar days after the day that your firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that it markets has malfunctioned and this device or a similar device that your firm markets would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, as required by 21 CFR 803.50(a)(2).

For example, based on the information included for Complaints #028 and 029, your firm became aware of these two events on May 11, 2015, and September 10, 2015 respectively, that associate your firm's osteotomy device and your firm's pin plate with a malfunction. The malfunction of long-term implantable devices is reportable. There is no evidence to justify whether the malfunctions would not be likely to cause or contribute to a death or serious injury, if they were to recur. Your firm did not submit MDR reports within 30 days of receiving or otherwise becoming aware of the referenced events.

Your response dated April 7, 2016, is not adequate. Your firm has not yet submitted evidence of implemented corrective actions that will allow your firm to meet the required reportability timeframes for the future submission of MDR reportable events.

8) Failure to implement written MDR procedures, as required by 21 CFR 803.17.

After reviewing your firm's MDR procedure, titled "Medical Device Reporting", Doc No: QOP8504, Rev B, Date 3/16/12, the following deficiencies were noted:

(a) QOP8504, Rev B does not establish internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements. For example:

i. Your procedure includes definitions for the terms caused or contributed," "malfunction," "MDR reportable event," and "serious injury," and the definition for the term "reasonably suggests," found in 803.20(c)(1). The procedure omits definition of the term "become aware" from 21 CFR Part 803.3. The exclusion of the definition for this term from the procedure may lead your firm to make an incorrect reportability decision when evaluating a complaint that may meet the criteria for reporting under 21 CFR 803.50(a).

(b) QOP8504, Rev B does not establish internal systems that provide for timely transmission of complete medical device reports. Specifically, the following are not addressed:

i. The circumstances under which your firm must submit supplemental or follow-up reports and the requirements for such reports.

ii. How your firm will submit all information reasonably known to it for each event. Specifically, which sections of the FDA Form 3500A will need to be completed to include all information found in the firm's possession and any information that becomes available as a result of a reasonable follow up within its firm.

(c) QOP8504, Rev B does not describe how your firm will address documentation and record-keeping requirements, including:

i. Documentation of adverse event related information maintained as MDR event files.

ii. Information that was evaluated to determine if an event was reportable.

iii. Documentation of the deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable.

iv. Systems that ensure access to information that facilitates timely follow-up and inspection by FDA.

Please note your firm's MDR procedure does not provide information about MDR reports in electronic format. Effective August 14, 2015, MDRs should be submitted to the FDA in an electronic format that the FDA can process, review and archive. Paper submissions will not be accepted, except under special circumstances directed by the FDA. Your firm should revise its MDR procedure accordingly to include a process for submitting MDRs electronically in accordance with the Final Rule for electronic Medical Device Reporting (eMDR) published in the Federal Register on February 14, 2014. In addition, your firm will need to establish an eMDR account in order to submit MDRs electronically. Information about the Final Rule for eMDR and the eMDR set-up process can be found on the FDA website at:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/Repo

The adequacy of your firm's response dated April 7, 2016 cannot be determined. Your firm plans to address the issues noted in the current MDR procedure. However, your firm did not provide an updated MDR procedure for review. Therefore, the adequacy of your firm's response could not be determined at this time.

9) Failure to submit a written report to FDA of any correction or removal of a device initiated to remedy a violation of the Act caused by the device which may present a risk to health, as required by 21 CFR Part 806.10.

For example, your firm initiated CAPA #0293, dated September 29, 2015, referencing

non- locking semi-tubular screw plate screws that were passing through the hole of the Semi-Tubular Bone Plates, Part # SMTP-10, allowing the screws to pass through the plates. You received
SMTP-10 plates from the field from September 1, 2015 through September 28, 2015. Your firm did not submit a written report to FDA of the removal, as required by 21 CFR 806.10.

We reviewed your firm's response, dated April 7, 2016, and it is not adequate. Your firm stated that you will generate a justification to demonstrate that the removal does not require Recall. However, CDRH classified a similar recall, where a bone screw went through a hole in a bone plating system. As of June 7, 2016, there is no record of Trimed, Inc. submitting a Report of Correction or Removal to FDA.

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. 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 devices 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, 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. Include special identifier FEI: 3001236812 on all correspondence.

Your response should be sent to:

CAPT Larry Howell
Acting Director, Compliance Branch
Food and Drug Administration
19701 Fairchild
Irvine, CA   92612-2506

If you have any questions about the content of this letter please contact: Dr. William Vitale, Compliance Officer at 949-608-2919.

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/
CDR Steven E. Porter, Jr.
Los Angeles District Director

Cc:

David M. Mazzera, Ph.D.
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