U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Storz Medical, AG 8/24/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

AUG 24 2010

WARNING LETTER

VIA UPS EXPRESS

Mr. Gerold Heine
Managing Director
Storz Medical, AG
Lohstampfestrasse 8
CH-8274 Tagerwilen
Switzerland

Dear Mr. Heine:

During an inspection of your firm located in Tagerwilen, Switzerland, on March 15, 2010, through March 19, 2010, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the Modulith SLK and Modulith SLX-F2 devices. 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 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 (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of federal Regulations (C.F.R.), Part 820. We received a response from Klaus Hugen, Director of Quality Management, dated March 29, 2010, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations that was issued to you. We acknowledge receipt of the additiona response dated April 26, 2010, however, this response was received after fifteen days of the close of the inspection and as a result, was not reviewed. We address the March 29, 2010, response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. 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, no protocol, including acceptance criteria, was established for the validation of Change Request **(b)(4)**. Additionally, there was no documentation showing that this change was validated. The change was implemented to fix cracked cooling pumps in the Modulith SLX-F2.

We reviewed your response and conclude that it is inadequate because you have not provided evidence of a correction, corrective action, or systemic corrective action. Your response indicates your intention to revise the procedure, Design and Technical Changes, and provide training on the procedure. You did not provide evidence of this revision or evidence of a systemic corrective action.

2. failure to establish and maintain adequate procedures to control product that does not meet specified

requirements, as required by 21 CFR 820.90(a). For example, your firm failed to follow procedure QMV_SMAG_002_01_02, Control of Nonconforming Products, in that there was no documentation of the evaluatio and disposition of the following pumps found defective ("intake cracked") during production: Serial numbers **(b)(4)**; **(b)(4)** and **(b)(4)**

We reviewed your response and conclude that that it is inadequate because you did not provide evidence of a correction, corrective action, or systemic corrective action. You indicate in your response that you will retrain employees on the onconforming Products procedure, but you have not provided evidence of this retraining or evidence of any additional corrective action or systemic corrective action.

3. Failure to establish and maintain adequate procedures to ensure that any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated unless such investigation has already been performed for a similar complaint and another investigation is not necessary, as required by 21 CFR 820.198(c). For example, your firm failed to extend the investigation into the causes of Complaint# **(b)(4)** to additional units exhibiting the same defect reported in the complaint. This complaint was opened on 11/14/09, following the receipt of Product Complaint Report# **(b)(4)** describing a crack at the inlet hose attachment of the cooling pump in Modulith SLX-F2 system. According to the complaint the system "was noticed to be leaking water." The complaint was investigated and closed on 3/15/10. During the complaint investigation three pumps with the same defect were detected in production. However, there is no documentation showing that these three units were evaluated and results or conclusions included or referred to in Complaint# **(b)(4)**

We reviewed your response and conclude that it is inadequate because you have not provided evidence of a correction, corrective action, or systemic corrective action. You indicate in your response the intention to revise your complaint procedure and provide training. Your firm indicated that a timeline regarding the nonconforming product in the observation was attached, but this could not be located within the response. Please provide evidence of the revised procedure, training, and any systemic corrective action that has been completed.

4. Failure to establish and maintain adequate procedures to ensure that the manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary and maintain a record that justifies when no investigation is performed, as required by 21 CFR 820.198(b). For example, the firm failed to conduct ar investigation into the causes of Complaint **(b)(4)**. This complaint was opened on 5/8/09, after receiving Product Complaint Report# **(b)(4)** from a US distributor, Product Complaint Report# **(b)(4)** reported "water leaking from the cooling pump" and a crack in the pump inlet port in the Modulith SLX-F2 system. The defective pump wa returned on 8/12/09 and the firm decided not to evaluate the complaint for investigation. Even without a documented investigation, including root cause, change request **(b)(4)** was initiated on 11/19/09 and approved on 1/18/10 to remediate the water leaking defect. Complaint **(b)(4)** was closed on 3/15/10. There is no documentation showing the reason not to investigate and the individual responsible for the decision.

We reviewed your response and conclude that it is inadequate because you have not provided evidence of a correction, corrective action, or systemic corrective action. In your response you acknowledge the need to revise your complaint procedure, but you did not provide this for review. You also did not provide any corrective action or systemic corrective action.

A follow up inspection will be required to assure that corrections arc adequate. An FDA trip planner will be in touch with you to arrange a mutually convenient date for this inspection.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action, which may include detaining your devices without physical examination upon entry into the United States until the corrections are completed. Section 801(a) of the Act (21 U.S.C. § 381(a)) Also, U.S 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 deviations 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 (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. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to: Matthew Krueger, WO-66 RM 3676, 10903 New Hampshire Avenue. Silver Spring,

Maryland 20993. If you have any questions about the content of this letter please contact: Amy Skrzypchak at (301) 796-5613 or amy.skrzypchak@fda.hhs.gov.

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 th inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance 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 your,

/S/
Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

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