U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Spiegelberg Gmbh & Co. KG 8/3/16

Department of Health and Human Services

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

WARNING LETTER
AUG 3, 2016

VIA UNITED PARCEL SERVICE

Frank Sodha
Managing Director
Spiegelberg Gmbh & Co. KG
Tempowerkring 4
Hamburg 21079
Germany

Dear Mr. Sodha:

During an inspection of your firm located in Hamburg, Germany, on February 1, 2016 through February 4, 2016, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures intercranial pressure monitoring products, including the ICP Monitor HMO 29.1, ICP Monitor HOM 29.2, ICP 3PS Probe, and ICP Probe 3PN. 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 requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received responses from Frank Sodha dated February 19, 2016 and March 8, 2016, and from Heige Jurchen dated March 18, 2016, 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 these responses 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 procedures for validating the device design, as required by 21 CFR 820.30(g). For example: your firm failed to adequately validate the design of ICP Monitor HOM 29.1 and ICP Monitor HMO 29.2. Your firm did not have a documented rationale for the decision not to perform validation activities.

We reviewed your firm's response and conclude that it is not adequate. The response indicates your firm anticipates completion of the design validation for ICP Monitor HOM 29.1 and ICP Monitor HMO 29.2. However, you firm's response does not include a review of other design changes or projects to determine if they were adequately validated.

2. Failure to establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product, as required by 21 CFR 820.90(b)(1). For example: review of device history records for the ICP 3PS

Probe revealed that 7 probe samples were visually inspected and one probe was functionally tested. The probe failed its functional test. Your firm did not document the disposition of the nonconforming probe.

The adequacy of your firm's response cannot be determined at this time. Your firm's response indicates that a new procedure will be established. However, your firm did not provide a procedure for review.

3. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). For example: a review of Error Guidance procedure **(b)(4)**, revealed that it did not adequately define and include the requirements for:

a. analyzing quality data to identify existing and potential causes of nonconforming product or other quality problems, using appropriate statistical methodology, where necessary;

b. disseminating information related to the quality problems and nonconforming product; and

c. submitting relevant information for management review.

We reviewed your firm's response and conclude that it is not adequate. The response indicates your firm will review internal databases for the need to open further CAPAs. However, the response did not include the new procedures. Additionally, your firm did not indicate if past CAPAs will be reviewed for adequacy, and remediated as necessary.

4. Failure to ensure that when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol, as required by 21 CFR 820.70(i). For example: your firm uses **(b)(4)** use.

We reviewed your firm's response and conclude that it is not adequate. The response indicates your firm will follow the guidance of "Off-The-Shelf Software Use in Medical Devices" **(b)(4)**, and if necessary, perform a validation. However, your firm did not provide sufficient details describing its corrective actions for assessment.

5. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). For example: when an ICP Monitor fails in-process or final functional testing, it is immediately repaired and retested. Your firm does not keep a record of the identified nonconformity and the actual failed test or inspection results.

The adequacy of your firm's response cannot be determined at this time. The response indicated your firm will revise procedures and conduct a retrospective review of internal data to identify nonconforming parts. Your firm did not provide procedures for review.

Our inspection also revealed that your firm's manufactures intercranial pressure monitoring devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information regarding the devices that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting. Significant deviations include, but are not limited to:

6. Failure to 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). A malfunction is reportable if the manufacturer takes or would be required to take an action under sections 518 or 519(g) of the Act, 21 U.S.C. § 360(h) and § 360(i)(g), as a result of the malfunction of the device or other similar devices.

For example: Your Customer Notification Letter, dated December 29, 2009, references a recall of the ICP Probe 3PN and ICP Probe 3PS due to a device malfunction. An MDR report was not submitted to the FDA within the 30 calendar day timeframe.

7. Failure to adequately develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17. For example: a review of "Processing Instruction 064", version 07 was conducted and we determined that the document does not contain information that would indicate that it was an MDR procedure created in accordance with the requirements in 21 CFR 803.17.

We reviewed your firm's response dated March 8, 2016, and conclude that it is not adequate. Your firm submitted a revised MDR procedure titled **(b)(4)** "MDR Reporting for FDA," version 1, effective date March 3, 2016. A review noted **(b)(4)**, version 1 does not establish internal systems that provide for timely transmission of complete medical device reports. Specifically, the circumstances under which your firm must submit supplemental or follow-up reports and the requirements for such reports is not addressed.

The procedure includes a reference to submit MDRs to FDA using the following address: FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847-3002. Please note that effective August 14, 2015, MDRs should be submitted electronically and paper submissions will not be accepted, except under special circumstances, as directed by FDA. For more information about electronic reporting, please refer to the eM DR website and the eM DR guidance document.

Additionally, your firm should adjust its MDR procedure 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. Information about the Final Rule for eMDR can be found on the FDA website at: **http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR%E2%80%93ElectronicMedicalDeviceReporting/default.htm (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR%E2%80%93ElectronicMedicalDeviceReporting/default.htm)**.

Our inspection also revealed that your firm's intercranial pressure monitoring devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 806 - Reports of Corrections and Removals. Significant violations include, but are not limited to, the following:

8. Failure to submit a written report to FDA of any correction or removal of a device initiated to reduce a risk to health posed by the device, as required by 21 CFR Part 806.10. For example, your firm performed a field correction and removal in 12/2009-01/2010 involving ICP Probe 3PN and ICP Probe 3PS, due to a complaint reporting shrinkage of the probe air-pouch resulting in false high ICP readings in the lower measuring ranges of 0-20 mmHg. The air-pouch production procedure was then revised **(b)(4)**. A letter was sent to customers notifying them of the issue and instructing them to return the affected devices. Your firm did not submit a written report to FDA of the correction and removal, as required by 21 CFR 806.10.

We reviewed your firm's response, dated February 19, 2016, and conclude that is not adequate. Your firm stated that they "thought that this information should have been disseminated by Aesculap Inc., and Aesculap Inc. decided not to do so." As of April 4th, there is no record of Spiegelberg Gmbh & Co. KG submitting a report of correction or removal to FDA.

The FDA also determined that the ICP Monitor HOM 29.2 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). The device is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm introduced or delivered for introduction into interstate commerce this device with a change or modification that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source or manufacturing process without submitting 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 modified the ICP Monitor HOM 29.1, cleared under K003759, by including a rechargeable battery in addition to the AC power supply source. A

change from AC to battery power is a change in energy source type. Additionally, such a change is usually part of a redesign to provide a portable device that can be used under different environmental conditions that the original device. Therefore, a new 510(k) is required for this change.

For a device requiring premarket approval, the notification required by section 510(k) is deemed satisfied when a PMA is pending before the agency. [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 /MedicaiDevices/DeviceRegulationandGuidance/HowtoMarket YourDevice/default.htm. The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

Given the serious nature of the violations of the Act, the ICP Monitor HOM 29.2 manufactured by your firm are subject to refusal of admission under section 801 (a) of the Act, 21 U.S. C. § 381 (a), in that they appear to be adulterated. As a result, FDA is taking steps to refuse entry of these devices into the United States, known as "detention without physical examination," until these violations are corrected. In order to remove the devices from detention, your firm should provide a written response to this Warning Letter as described below and correct the violation(s) described in this letter. 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.

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 #495642 when replying. If you have any questions about the contents of this letter, please contact: Daniel Walter, Chief, Foreign Enforcement Branch, at CDRHOCWarningletterResoonses@fda.hhs.gov (email) or +1 (240) 402-4020 (telephone).

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
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