EMcision Ltd. 11/20/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
White Oak Building 66
Silver Spring, MD 20993

WARNING LETTER
NOV 20, 2014

VIA UNITED PARCEL SERVICE

Cherif Habib
Chief Executive Officer

EMcision Ltd.
Liver Surgery Sec., Hammersmith Hospital
Du Cane Road
London W12 0HS
United Kingdom

Dear Mr. Habib:

During an inspection of your firm located in London, United Kingdom,on August 11, 2014, through August 14, 2014, an investigator from the United States Food and Drug Administration (FDA) determined that your firm is the specifications developer for the Habib EndoHPB. 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.

Our inspection revealed that the Habib EndoHPB is 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 (MDR). Significant deviations include, but are not limited to:

Failure to develop, maintain and implement written MDR procedures as required by 21 CFR 803.17. Your firm's MDR procedure lacks the following:

1. Internal systems that provide for:

a. Timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements. For example, your firm's procedure omits the definition of the term "become aware," found in 21 CFR 803.3. The exclusion of the definition of 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. A standardized review process to determine when an event meets the criteria for reporting under this part. For example:

i. Your firm's procedure, as written does not specify who makes the decision for reporting events to FDA; and

ii. There are no instructions for how your firm will evaluate information about an event to make MDR reportability determinations in a timely manner.

c. Timely transmission of complete medical device reports. Your firm's procedure does not include or refer to instructions for how to complete the FDA 3500A form.

2. A description of how your firm will address documentation and record-keeping requirements, including:

a. Documentation of adverse event related information maintained as MDR event files;

b. Information that was evaluated to determine if an event was reportable;

c. 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; and

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

We reviewed your firm's response dated August 29, 2014, and conclude that the adequacy of the response cannot be determined at this time. Your firm stated that it will revise its MDR procedure and submit a copy of the revised procedure when the revisions and training for the procedure are completed. FDA cannot make an assessment with respect to adequacy of your firm's response until we receive a copy of the revised procedure.

The eMDR Final Rule requiring manufacturers and importers to submit electronic Medical Device Reports (eMDRs) to FDA was published on February 13, 2014. The requirements of this final rule will take effect on August 14, 2015. If your firm is not currently submitting reports electronically, we encourage you to visit the following web link for additional information about the electronic reporting requirements:

http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm

If your firm wishes to discuss MDR reportability criteria or to schedule further communications, it may contact the Reportability Review Team by email at

ReportabilityReviewTeam@fda.hhs.gov

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.

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 responses and the need to re-inspect your firm's facility to verify that the appropriate corrections and/or corrective actions have been made.

In addition, FDA has noted nonconformances with regards to section 501(h) of the Act, 21 U.S.C. § 351(h), which are deficiencies within your firm's quality system pertaining to current good manufacturing practice requirements specified in the Quality System regulation found at 21 CFR Part 820. These nonconformities include, but are not limited to, the following:

1. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA), as required by 21 CFR 820.100(a). For example, your firm's CAPA procedure lacks requirements for:

a. Analyzing quality records, service records and complaints, and other sources of quality data to identify the existing and potential causes of nonconforming product or other quality problems;

b. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems; and

c. Identifying the actions needed to correct and prevent recurrence of nonconforming product and other quality problems.

The adequacy of your firm's response cannot be determined at this time. Your firm's response did not state when your firm expects to complete and submit evidence of implementation of its corrective actions.

2. Failure to maintain complaint files and establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example:

a. Your firm's current complaint handlingprocedure does not ensure that:

i. All complaints are processed in a uniform and timely manner;

ii. Oral complaints are documented upon receipt; and

iii. Complaints are evaluated to determine if the complaint is required to be reported to FDA under 21 CFR 803, Medical Device Reporting.

b. Your firm did not document MDR reportability evaluation in accordance with its complaint handlingprocedure. For example, the MDR evaluation section was left blank for complaint numbers 2013-014 and 2014-001.

c. Your firm failed to follow its 2007 complaint handling procedure, since a review of the following complaint records found:

i. Complaint # 2012-001 was missing dates and signatures of the approval officials;

ii. Complaint #s 2013-005 and 2013-005 had no entry for complaint category; and

iii. Complaint # 2013-007 had no entry for complaint receipt date and complaint category.

The adequacy of your firm's response cannot be determined at this time. Your firm's response did not state when your firm expects to complete and submit evidence of implementation of its corrective actions.

3. Failure to document all activities and their results, as required by 21 CFR 820.100(b). For example, eight CAPAs initiated between 2009 and 2013 were reviewed during the inspection. All CAPAs were missing some documentation, contained conflicting information, or had no signatures.

The adequacy of your firm's response cannot be determined at this time. Your firm's response did not state when your firm expects to complete and submit evidence of implementation of its corrective actions.

4. Failure to establish and maintain procedures for the identification, documentation, validation, or, where appropriate, verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i). For example, a review of your firm's Engineering Change Notices (ECNs) found several ECNs that did not include documentation of the design change, dates, or approval signature, as required by your firm's Design Control procedure.

The adequacy of your firm's response cannot be determined at this time. Your firm's response did not state when your firm expects to complete and submit evidence of implementation of its corrective actions

5. Failure to establish and maintain procedures to control all documents, as required by 21 CFR 820.40. For example, your firm failed to follow its Documentation Management proceduresince it used electronic signatures to approve numerous procedures. Your firm's procedure states that there are no currently-approved electronic signature systems implemented at your firm.

The adequacy of your firm's response cannot be determined at this time. Your firm's response did not state when your firm expects to complete and submit evidence of implementation of its corrective actions

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 2622, 10903 New Hampshire Ave., Silver Spring, MD 20993. Refer to CMS case # 440200 when replying. If you have any questions about the contents of this letter, please contact: Daniel Walter, Chief, Foreign Enforcement Branch, by telephone (301) 796-5587;or by fax (301) 847-8139.

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/
Steven D. Silverman
Director
Office of Compliance

Center for Devices and
Radiological Health

More in Compliance Actions and Activities

- Warning Letters
- 2015
- 2014
- 2013
- 2012
- 2011
- 2010
- 2009
- 2008
- 2007
- 2006
- 2005

Tobacco Retailer Warning Letters

Page Last Updated: 05/07/2015
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

Contact FDA