Olympus Corporation of the Americas 8/12/15

Department of Health and Human Services

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

WARNING LETTER
AUG 12, 2015

VIA UNITED PARCEL SERVICE

Akihiro Okubo, President
Olympus Medical Systems Corporation
2951 Ishikawa-cho, Hachioji-shi
Tokyo 192-8507, Japan

Dear Mr. Okubo:

The United States Food and Drug Administration (FDA) conducted inspections at your following facilities:

- Olympus Medical Systems Corporation, located at 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan, on April 20, 2015 through April 24, 2015;
- Aizu Olympus Co., Ltd., located at 500 Aza Muranishi Ooaza, Niidera, Monden-Machi, Aizuwakamatsu-shi, Fukushima 965-8520, Japan, on April 13, 2015 through April 17, 2015;

- Olympus Corporation of the Americas, located at 3500 Corporate Parkway, Center Valley, Pennsylvania 18034, U.S.A., on March 25, 2015 through April 1, 2015; and
- Olympus Corporation of the Americas, located at 2400 Ringwood Avenue, San Jose, California 95131, U.S.A., on March 19, 2015 through April 2, 2015.

During these inspections investigators from the FDA determined that your firm manufactures endoscopes and endoscope accessories. 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.

Our inspections revealed that the duodenovideoscope Olympus TJF Type Q-180V 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 respecting the device 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:

1. 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 your firm markets may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a)(1).

For example, Complaint #GIR/OBV-11055 references 16 patients who contracted a Pseudomonas aeruginosa infection, of which some resulted in abscesses, after undergoing an endoscopic procedure with your firm's devices. Your firm submitted one MDR (MDR #8010047-2015-00218) to account for all the patients involved in the event. Your firm failed to submit an initial MDR for each event referencing patients sustaining abscesses as a result of contracting a Pseudomonas aeruginosa infection after undergoing an endoscopic procedure involving your firm's devices. Your firm became aware of the event on May 16, 2012. The referenced MDR and all additional MDRs associated with the event were received by FDA in 2015, which is beyond the 30 calendar day timeframe.

We received a response from Mr. Akihiro Okubo, President, and Hisao Yabe, Division Manager, Medical Quality and Regulatory Division, dated May 14, 2015, concerning our investigators' observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations that was issued to your firm. The adequacy of your firm's response cannot be determined at this time. Your firm described its corrective actions. However, it did not include documentation or evidence of the corrective actions and did not provide evidence of implementation with the response to FDA. Without this documentation, FDA is unable to make an assessment with respect to adequacy.

2. Failure to adequately develop, maintain and implement written MDR procedures, as required by 21 CFR 803.17(a)(3). For example, after reviewing your firm's MDR procedure, "MDR Processing," **(b)(4),** and identified as Version 18, Dated: March 27, 2015, the following issue was noted:

a. The procedure does not establish internal systems that provide for timely transmission of complete medical device reports. Specifically, the following are not addressed:

i. How your firm will submit all information reasonably known to it for each event.

ii. The procedure does not contain or refer to instructions for how to obtain and complete the FDA 3500A form.

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 actions (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.

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 #470191 when replying. If you have any questions

about the contents of this letter, please contact: Ronald Swann, Chief, Abdominal and Surgical Devices Branch, at +1 (301) 796-5469, or fax +1 (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 facilities. 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 inspections 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/
Jan B. Welch, MHS, MT (ASCP) SBB
Acting Director
Office of Compliance
Center for Devices and Radiological Health

Cc:

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1-888-INFO-FDA (1-888-463-6332)

Contact FDA