DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 594-4695 Fax:(301) 594-4715 Industry Information: www.fda.gov/oc/industry	04/20/2015 - 04/24/2015
	FEI NUMBER 3002807795

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Akihiro Okubo, President and Representative Director

FIRM NAME	STREET ADDRESS
Olympus Medical Systems Corporation	2951 Ishikawa-Cho
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hachioji-Shi 192-8507, Japan	Specification Developer/Headquarters

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically, (b) Medical Device Reports (MDR's) were reported late by Olympus Medical Systems Corporation (OMSC) specific to the TJF-Q180V duodenoscope related to infection/contamination, January 1, 2010 to March 31, 2015. The TJF-Q180V duodenoscope is the same model that is sold in United States. OMSC is responsible for international complaints requiring MDR submission to FDA. The following are three examples of the (b) provided by the firm for late submission.

MDR #	Date Aware	Date Submitted to FDA	Days Late
8010047-2015-00210	11/21/2013	3/16/2015	450
8010047-2015-00218	4/26/2012	3/13/2015	1021
8010047-2015-00282	6/12/2014	3/31/2015	262

OBSERVATION 2

Corrective and preventive action activities and/or results have not been adequately documented.

Specifically, Olympus Medical Systems Corporation (OMSC) conducted a review of Medical Device Reporting (MDR). OSMC's review required the correction of MDRs that were incorrectly submitted where multiple patient complaints were under one MDR. The TJF-Q180V duodenoscope related to infection/contamination was identified in these MDRs and is the same model that is sold in the United States. MDRs 8010047-2015-00216 through 8010047-2015-00230 and 8010047-2015-00232 through 8010047-2015-00237 was submitted on 3/13/2015 as a corrective action without generating a Corrective and Preventive Action (CAPA).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Stephen C. Smith, Investigator Maida Henesian, Investigator	04/24/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 594-4695 Fax:(301) 594-4715 Industry Information: www.fda.gov/oc/industry	04/20/2015 - 04/24/2015
	FEI NUMBER 3002807795

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Akihiro Okubo, President and Representative Director

FIRM NAME	STREET ADDRESS
Olympus Medical Systems Corporation	2951 Ishikawa-Cho
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hachioji-Shi 192-8507, Japan	Specification Developer/Headquarters

Observation Annotations

Observation 1: Promised to correct.

Observation 2: Promised to correct.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Stephen C. Smith, Investigator Maida Henesian, Investigator	04/24/2015