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	04/13/2015 - 04/17/2015
	FEI NUMBER 3002964398

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kazuhisa Otani, President

FIRM NAME	STREET ADDRESS
Aizu Olympus Co., Ltd.	500 Aza Muranishi Oaza-Niidera, Monden-Machi
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Aizuwakamatsu-City, Fukushima 965-8520, Japan	manufacturing

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

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

Specifically, a new manufacturing process was added for TJF-Q180V final assembly. Water Leak Test, method #: (b) (4), Date: 2015-3 26, was developed as a preventive action without generating a Corrective and Preventative Action.

OBSERVATION 2

A device history record has not been maintained.

1. Specifically, eleven out of (b) (4) device history records reviewed for the TJF-Q180V Duodenoscopes did not include or refer to the location of, the primary identification label and labeling used for each production unit. For example the following (b) (4) DHR's were provided and lacked labels: (b) (4)

2. Specifically, the device history record reviewed for the TJF-Q180V Duodenoscopes did not reference the revision number of the procedure used to create the control units that is part of the final assembly for serial number (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Stephen C. Smith, Investigator Maida Henesian, Investigator	04/17/2015

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Observation Annotations

Observation 1: Promised to correct.

Observation 2: Promised to correct.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Stephen C. Smith, Investigator
Maida Henesian, Investigator

DATE ISSUED

04/17/2015