

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 594-4695 Fax: (301) 594-4715 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 04/13/2015 - 04/20/2015
	FEI NUMBER 3010516924

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Yasuharu Seki, General Manager Endoscope Production Headquarters

FIRM NAME Fujifilm Optics Co. Ltd. Mito	STREET ADDRESS 4112 Tono
CITY, STATE, ZIP CODE, COUNTRY Hitachiomiya City 3192224, Japan	TYPE ESTABLISHMENT INSPECTED Manufacturer

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

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically, your firm did not conduct a risk analysis of the duodenoscope model ED-530XT units remaining on the market which were manufactured using an un-validated process. Your firm did not conduct process validation of the critical sub-assemblies (b)(4) that are part of the manufacturing of the duodenoscope ED-530XT until January 2014. Your firm began commercially distributing model ED-530XT in February 2007.

OBSERVATION 2

Process control procedures that describe any process controls necessary to ensure conformance to specifications have not been adequately established.

Specifically,

A. Your firm failed to follow your approved procedure (b)(4) *Assembling Manual for the (b)(4)* (b)(4) for section including but not limited to (b)(4) which states the (b)(4). The procedure does not specify a (b)(4), but you stated you follow the product specification sheet for (b)(4) which states that (b)(4) (b)(4)

Although your firm conducted a verification experiment to (b)(4) (b)(4) your procedure (b)(4) does not state or refer to any documentation stating that your firm may use a (b)(4). In addition, although your firm utilizes (b)(4) (b)(4) your device history records do not document the time and temperature parameters of the (b)(4)

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OBSERVATION 5

Procedures for training and identifying training needs have not been adequately established.

Specifically, procedures (b)(4) *Employees and Standard Training* and (b)(4) *Provisions on Education and Training* which govern training do not include the training needs for personnel who engage in the manufacturing of medical devices including duodenoscopes. Training forms "Educational Record according to Individual", "Skill Record Table according to Individual", "Plan for Versatile Worker" and "Plan of new employee education" do not document the training needs, but only document the procedure and/or the process for the employee to be trained to, and the number of days it should take the employee to reach a particular final proficiency. The procedures do not specify skills the employee must be proficient in, or how to evaluate the employee to determine proficiency in those skills needed to properly perform the necessary actions to manufacture medical devices including duodenoscopes.

OBSERVATION 6

Calibration procedures do not include provisions for remedial action.

Specifically, your calibration procedures (b)(4) *Provisions on measuring equipment control for medical devices* and (b)(4) *Measuring Equipment Control Standard* do not specify provisions for remedial actions if equipment is found out of calibration including the opening of an investigation and the evaluation of components/finished devices which may have been affected.

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Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Promised to correct.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct.
Observation 5:	Promised to correct.	Observation 6:	Promised to correct.

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