DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Avenue			2015	
Silver Spring, MD 20993 (301) 594-4695 Fax:(301) 594-4715 Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		04/13/2015 - 04/20/2015 FEINUMBER 3010516924		
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  TO: Yasuharu Seki, General Manager Endos		ion Headquarters		
FIRM NAME Fujifilm Optics Co. Ltd. Mito	street address 4112 Tono	<u>.</u>		
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.				
A. Your firm failed to follow your approved procedure (b)(4)  (b)(4)  (b)(4)  (c)  (d)  (e)  (e)  (for section including but not limited to (b)(4)  (for section including but not limited to (b)(4)				
your device history records do not your device history records do not a your device history records do not your device hi	document the tim			

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for each device, and you do not record the time of the operations in the device history record.					
B. Your firm failed to properly define ambiguous terms used in procedure $\binom{b}{4}$ Assembling Manual for the $\binom{b}{4}$					

B. Your firm failed to properly	define ambiguous terms us	ed in procedure $\frac{(b)(4)}{(b)}$	Assembling Manual for the (b)
(b)(4)	including	(b)(4)	
(b)(4)			
(b)(4)	Section (b) of procedur	$e^{(b)(4)}$ step	(states (b)(4)
(b)(4)			
<i>(b)(4)</i>			<ol> <li>The device history records for ED-530</li> </ol>
XT do not show $(b)(4)$		. Your	firm defined the terminology used in the
step as $(b)(4)$			
(b)(4), but was unable to pro-	vide objective evidence to	this meaning of the word	

# **OBSERVATION 3**

Procedures for acceptance activities have not been adequately established.

Specifically,

- A). Your firm has not established procedures or specifications for acceptance of the (b)(4) material which is used for the critical sub-assemblies which are in turn used for final assembly of your endoscopes and duodenoscope model ED-530XT. Your firm has not ensured that each lot of (b)(4) material received has the same properties as the solder used during process validation (b)(4).
- B). Your firm's incoming acceptance activities for components at your site are not documented in a procedure. There is no procedure in place requiring your firm to examine incoming components for evidence of damage while in transit from your sister company to your facility.

## **OBSERVATION 4**

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

Specifically, your firm's procedures, (b)(4) , MQS Provisions on Selecting and Evaluating Medical Device Cooperative Companies, Rev (b) and (b)(4) , Purchasing Control Standards, do not include the requirement for the auditor to document/assess what critical processes (b)(4) ) or elements are required to be covered during the audit used for supplier qualification. In addition, your procedures do not require critical suppliers to provide evidence that they have control of their critical processes and are able to meet quality requirements. Furthermore, your suppliers are categorized based on the number of delivered lots and nonconformity rate rather than criticality.

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Manufacturer

### **OBSERVATION 5**

Hitachiomiya City 3192224,

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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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Yasuharu Seki, General Manager Endoscope Production Headquarters

FIRM NAME

STREET ADDRESS

Fujifilm Optics Co. Ltd. Mito

CITY, STATE, ZIP CODE, COUNTRY

Hitachiomiya City 3192224, Japan

Manufacturer

**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.

EMPLOYEE(S) SIGNATURE DATE ISSUED

SEE REVERSE OF THIS PAGE Dawn M. McCabe, Investigator Ashley A. Mutawakkil, Investigator

04/20/2015

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