

**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: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>		DATE(S) OF INSPECTION 04/23/2015 - 05/01/2015 FEI NUMBER 3011324513
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED <b>TO: Kiyoshi (nmi) Inaba, Divisional Manager, QA and Reg Affairs Div., Medical Systems</b>		
FIRM NAME FujiFilm	STREET ADDRESS Kaisei-Machi, Miyanodai 798	
CITY, STATE, ZIP CODE, COUNTRY Ashigarakami Gun , Japan	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer	
<p>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.</p> <p><i>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.</i></p>		
<b>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:</b>		
<b>OBSERVATION 1</b>		
A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.		
Specifically,		
A. Your 2014 reprocessing validation for the duodenoscope model ED-530XT did not include evaluating the (b)(4) (b)(4). In addition, your firm only conducted (b)(4) (b)(4) of EO sterilization for validation and did not provide justification as to how (b)(4) is indicative of the process being consistent and reproducible. This reprocessing validation is being used to also support user instructions for the closed channel duodenoscope models: ED-250XT5, ED-250XL5, ED-450XT5, and ED-450XL5.		
B. Your 2002 reprocessing validation for the closed channel duodenoscope models (ED-250XT5, ED-250XL5, ED-450XT5, and ED-450XL5) includes the following deficiencies:		
<ul style="list-style-type: none"> <li>• Validation was performed on channel mockups and not the actual complete duodenoscope device. The distal tip of the duodenoscope was not evaluated.</li> <li>• No independent cleaning validation performed.</li> <li>• The validation included the use of a (b)(4) Product instead of a (b)(4)</li> <li>• The ethylene oxide (EO) sterilization results did not demonstrate a (b)(4)</li> <li>• The EO sterilization was conducted in a (b)(4) for which there was no established acceptance criterion for critical parameters such as EO concentration and humidity. In addition, no (b)(4) (b)(4) was performed and the aeration time/temperature found in the closed channel model user manuals were not validated.</li> </ul>		
<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Dawn M. McCabe, Investigator	DATE ISSUED 05/01/2015
	Ashley A. Mutawakkil, Investigator	
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C. Your 1998 reprocessing validation which your firm states covers all the open channel models (i.e. ED-200XU, ED-420XL, and ED-450XT) did not include the following:

- Written justification regarding how the validation is applicable to all U.S. marketed open channel duodenoscope user manuals since all three reprocessing manuals were approved prior to 1998.
- Validation was performed on channel mockups and not the actual complete duodenoscope device. The open channel model distal tip of the duodenoscope was not evaluated.
- No independent cleaning validation performed.
- The steam sterilization cycle included in the reprocessing user manual for sterilizing accessories was not validated.
- The EO sterilization did not include acceptance criteria for critical parameters such as EO concentration and humidity. In addition EO and BCH residual testing was not performed and aeration was not validated.


**OBSERVATION 2**

Procedures for design verification have not been adequately established.

Specifically,

A. During ED-250XT, ED-450XT, and ED-530XT duodenoscope model durability studies, the firm did not disassemble the distal tip end to examine the (b)(4).  
The firm only conducted an air-leak test which entails visually looking for air bubbles and has not ensured the leak test will detect a worn seal 100% of the time.

B. The firm's chemical resistance testing (material compatibility) for the (b)(4) utilized in the closed model duodenoscopes only included an evaluation of the (b)(4). Additional physical characteristics including, but not limited to evaluating the weight, elasticity, compression, and dimensions prior to the (b)(4) was not conducted. Only the external appearance was examined during the chemical resistance testing of the other ED-530XT component materials (b)(4).  
Furthermore, the firm has not evaluated the critical components of the closed channel models in order to determine approximately how many high level disinfection cycles or EO sterilization cycles they can undergo before the components need to be replaced.

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C. As part of design verification, your firm failed to evaluate potential reactivity of the (b)(4) to ensure there is no deterioration effect that may affect the integrity of the seal.

D. Your firm has not adequately verified the leak test method that is found in your duodenoscope user manuals, as well as supplementary material provided to end users including the *Fuji-1060 Endoscope Cleaning Poster 12-10-10* and the *Reprocessing Summary and Guide for Fujinon/Fujifilm Flexible GI Endoscopes*. You state you are following ISO 8600-7:2012, but this standard requires the submersion test be performed for at least one minute. Your user manuals and supplemental materials do not require the submersion test to be performed for at least one minute.

E. Your firm has not adequately verified that your (b)(4) tester is appropriate for use in performing an adequate air leak test for all of your endoscope models with ventilation connectors. You performed verification utilizing prototype (b)(4) devices on Gastroscope model EG-450WR5, but label that the equipment is applicable to all endoscopes with a ventilation connector.

**OBSERVATION 3**

The design was not validated under actual or simulated use conditions.

Specifically,

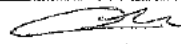

- A. Your 2014 and 2002 reprocessing validations (for closed channel models) and 1998 reprocessing validation (for open channel models) for the user instructions did not include user reprocessing validation studies to ensure the reprocessing instructions can be adhered to and are adequate for their intended use.
- B. Your firm did not include complete cycle parameters in your reprocessing user manuals (i.e. sterilizer size or load size validated) in order for the user to adequately assess if the sterilization cycle listed is appropriate for their use.

**OBSERVATION 4**

Procedures for corrective and preventive action have not been adequately established.

Specifically,

- A. Your procedures (b)(4) *Corrective and Preventive Action* and (b)(4) *Complaint Handling for Medical Device* do not contain provisions which allow CAPAs to be opened while the Complaint is still in the investigation phase, preventing the implementation of corrective and/or preventive actions. In addition, even though your procedure (b)(4)

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*Corrective and Preventive Action* states that one of the main information sources for corrective and preventive actions include information reported from service-related functions, and further states: (b)(4)

(b)(4) and register it in the CAPA system DB even if quality issues are detected., because you are not trending the information from your service and repair facilities, you are not appropriately initiating these CAPAs.

B. You failed to initiate a CAPA to determine whether or not customers who purchased your open model endoscopes, including but not limited to models ED-200XU, ED-420XL, and ED-450XT, still had them in use before deciding not to re-validate the reprocessing instructions in the open model endoscope user manuals.

C. You are not documenting the criteria for effectiveness checks and you did not perform adequate effectiveness checks for your CAPAs including but not limited to (b)(4)

**OBSERVATION 5**

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically,

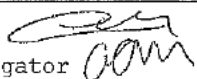

A. Your firm does not have procedures to ensure that your repair/servicing facilities are appropriately elevating servicing/repair data for complaint analysis.

B. Your firm failed to follow your procedure (b)(4) *Complaint Handling for Medical Device*. Procedure (b)(4) states that a complain (b)(4)

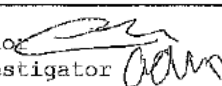
(b)(4) Section (b) Complaint Sources states (b)(4) your firm failed to investigate alleged deficiencies reported by your servicing/repair facilities. For example:

1. Device EG-530WR Serial Number (b)(4) was reported with description *BSA@DTA side, worn out, BSA Damaged inner parts, Part degradation, BSA – replace BSA w/ FCT/AWT/RBS Assembling failure* and was not investigated as a complaint and did not have justification why it was not investigated.

2. Device EG-530WR Serial Number (b)(4) was reported with description *New stock EG-530WR disables*

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<p><i>light control on 4400 and 4440, and th failure has reproduced. (ALC did not operate normally) and was not investigated as a complaint and did not have justification why it was not investigated.</i></p> <p>3. Devices EC-530HL2 Serial Number (b)(4) and EC-530LS2 Serial Number (b)(4) were reported with description <i>The prism separation was confirmed during incoming inspection from Japan as complaint 12712. The article investigation is hoped for at the Mito facility and was not investigated as a complaint and did not have justification why it was not investigated.</i></p> <p>C. Your firm utilizes "trouble reports" to receive data from your servicing and repair facilities, including those contained in Complaints (b)(4) and (b)(4). There is no procedure for repair/servicing companies to submit servicing and/or repairs for Complaint determination, or to alert you to a repair/service which they believe rises to the level of Complaint status. Once you receive these "trouble reports" your procedure (b)(4) <i>Complaint Handling for Medical Device</i> does not have instructions on how to evaluate them or elevate them for complaint determination.</p> <p>D. Your firm failed to evaluate the incoming complaint data and service data for the ED-530XT duodenoscope received from your sister facility out of (b)(4) in order to assess the need to open CAPAs to address the failures (i.e. distal end cap failure, peeled surface components, and fluid invasion) and determine if the failure is attributed to a design failure or manufacturing failure.</p>		
<b>OBSERVATION 6</b>		
Procedures for design change have not been adequately established.		
Specifically, your firm's 2009 design change assessment regarding changing the distal cap material from (b)(4) Product (b)(4) Product material did not include: (b)(4) Product (b)(4) Product		
<ul style="list-style-type: none"> <li>• Evaluating if the change impacts the safety of the device by conducting an assessment.</li> <li>• Durability testing of the hard plastic cap regarding EO sterilization.</li> <li>• Determining whether process validation is required.</li> <li>• Determining if the new material is effective in preventing the trapping of material between the fixed cap and elevator.</li> </ul>		
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**OBSERVATION 7**

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

Specifically,

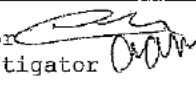
A. You did not follow your procedures (b)(4) Purchase Control Regulations and (b)(4) Endoscope System Special Supplier Review for evaluating the companies you utilize for servicing and repair operations for your endoscope models, including duodenoscopes, which are also distributed within the United States. In addition, your purchasing control procedures do not contain specific criteria for properly evaluating these companies you utilize for servicing and repair of after-market endoscopes.

You have quality agreements for only 11 out of (b) companies that you utilize for servicing/repairs. Ten (10) of these eleven (b) quality agreements state that the servicing company must have Complaint procedures in place. You have not audited these facilities to ensure they have these procedures. You have not performed on-site audits to include coverage of each company's ability to properly elevate the servicing and/or repairing of endoscopes for Complaint initiation.

B. The quality agreements you have in place with eleven (11) out of (b)(4) companies do not cover the full time period for which you utilized these companies for servicing and/or repair as well as Complaint determination. For example,

1. Your quality agreement with company (b) located in (b) was dated 1 September 2013, but this company has been providing servicing and repairs for duodenoscope models ED-250XT5 and ED-450XT5 since January 2009 and ED-530XT since December 2009.
2. Your quality agreement with company (b) located in (b)(4) was dated 1 August 2012, but this company has been providing servicing and repairs for duodenoscope Models ED-250XT5 since January 2009 and ED-530XT since December 2008.
3. Your quality agreement with company (b) located in (b)(4) was dated 1 August 2012, but this company has been providing servicing and repairs for duodenoscope models ED-250XT5 since January 2009 and ED-530XT since December 2008.

C. Your firm has no procedures for training the servicing/repair facilities personnel to ensure they are properly reviewing services/repairs for Complaint determination. Your procedure (b)(4) Implementation/Control of Medical Device Servicing Training does not contain provisions to train servicing personnel on how to evaluate of servicing or repairs should be elevated to Complaint status.

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**OBSERVATION 8**

Procedures for the use and removal of manufacturing material have not been adequately established.

Specifically, your firm did not segregate or determine the worst case materials (b)(4) Manufacturing Process during (b)(4) testing in order to ensure proper aeration time for the 2014 EO sterilization validation conducted to support the duodenoscope model ED-530XT user manual.

**OBSERVATION 9**

Service reports were not analyzed following appropriate statistical methods.

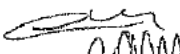
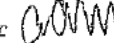
Specifically,

A. Your service data received from your sister facilities related to endoscopes including duodenoscopes is trended on a monthly basis and is not analyzed across multiple months in order to identify possible trends. In addition failure codes are quantified on a monthly basis for all models only which does not allow your firm to detect possible trends within specific models.

B. Your firm does not receive service and/or repair data for (b)(4) of companies utilized for the servicing and/or repair for your endoscopes models, including but not limited to (b)(4) of endoscope models (ED-250 XT5, ED-450XT5, ED-250XL5, ED-450XL5, ED-530XT), which are also distributed within the United States.

C. Procedure (b)(4) Complaint Handling for Medical Device section (b)(4) Complaint Sources states that (b)(4) Your firm failed to perform trend analysis on service reports for complaint determination.

D. Your firm is not performing adequate review of all service/repair data for Complaint determination. For example, when service/repair data is received from companies you contract with to perform these operations, your review consists of (b)(4) (b)(4) (b)(4) Complaint investigations were not initiated for units EG-530WR SN (b)(4) EG-590WR SN (b)(4) and EG-590WR SN (b)(4)

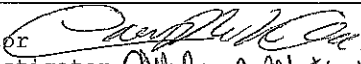
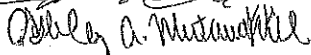
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**Observation Annotations**

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.
Observation 7:	Promised to correct.	Observation 8:	Promised to correct.
Observation 9:	Promised to correct.		

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