

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

| | |
|--|---|
| DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry | DATE(S) OF INSPECTION 03/24/2015 - 04/09/2015* |
| | FEI NUMBER 2431293 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Keiichi Nagata, President

| | |
|--|---|
| FIRM NAME Fujifilm Medical Systems U.S.A., Inc. | STREET ADDRESS 10 Highpoint Drive |
| CITY, STATE, ZIP CODE, COUNTRY Wayne, NJ 07470-7431 | TYPE ESTABLISHMENT INSPECTED Medical Device 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 I OBSERVED:

Corrective and Preventive Actions (CAPA)

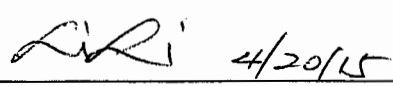
OBSERVATION 1

Complaints involving the possible failure of a device and labeling to meet any of its specifications were not reviewed, evaluated, and investigated where necessary.

Specifically,

- A. QA-020, Handling Customer Complaints, Rev. 0.02, effective 2/5/14, requires that any complaints involving the failure of a device, labeling, or packaging to meet its specifications must be investigated. However, QA-002, Reporting Customer Complaints, Rev. 0.02, effective 10/4/13, does not require that a complaint record is generated for any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution. QA-002 indicates that a complaint record is not required for device failures due to [REDACTED]", [REDACTED]", and [REDACTED]".
- B. There is a lack of investigations into failed, returned, and repaired duodenoscopes:
 - a. Work Order, RMA No. RP1501140028@@1, indicates that the Scope Body of ED-530XT, Serial No. 4D102A048, was damaged by fluid and there were bubbles from the control dials. The unit was repaired on 2/3/15.
 - b. Work Order, RMA No. RP1403180012@@1, indicates that ED-530XT, Serial No. 5D102A510, had a damaged Light Guide Probe Assembly, Video Connector Assembly, [REDACTED] (b) (4). The Light Guide Connector [REDACTED] (b) (4) had a "fluid invasion". The unit was repaired on 4/22/14.

AMENDMENT 1

| | | |
|---------------------------------|--|---------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE Li Li, Investigator | DATE ISSUED 04/20/2015 |
| |  | |

(b) (4)

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

| | |
|--|---|
| DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry | DATE(S) OF INSPECTION 03/24/2015 - 04/09/2015* |
| | FEI NUMBER 2431293 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Keiichi Nagata, President

| | |
|--|---|
| FIRM NAME Fujifilm Medical Systems U.S.A., Inc. | STREET ADDRESS 10 Highpoint Drive |
| CITY, STATE, ZIP CODE, COUNTRY Wayne, NJ 07470-7431 | TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer |

- c. Work Order, RMA No. RP1309170104@@1, indicates that ED-450XT5, Serial No. 1D080A030, had a leak at (b) (4). The unit was repaired on 10/22/13.

OBSERVATION 2

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

Specifically, RC-001, Reportable Adverse Events, Rev. 0.02, effective 6/20/14, requires that all customer complaints / incidents and other customer feedback be reviewed to determine whether they represent a reportable event for Medical Device Reporting (MDR). There is a lack of a MDR reportability review for the firm's work orders generated for repairing returned malfunctioned duodenoscopes.

- A. Work Order, RMA No. RP1501140028@@1, closed 2/3/15, indicates that the Scope Body of ED-530XT, Serial No. 4D102A048, was damaged by fluid and there were bubbles from the control dials.
- B. Work Order, RMA No. RP1403180012@@1, closed 4/22/14, indicates that ED-530XT, Serial No. 5D102A510, had a damaged Light Guide Probe Assembly, Video Connector Assembly, and (b) (4). The Light Guide Connector (b) (4) (b) (4) had a "fluid invasion".
- C. Work Order, RMA No. RP1309170104@@1, closed 10/22/13, indicates that ED-450XT5, Serial No. 1D080A030, had a leak at (b) (4).

OBSERVATION 3

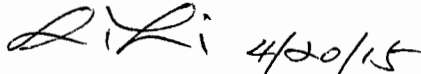
Procedures for corrective and preventive action have not been adequately established.

Specifically,

- A. QA-006, Corrective Actions / Preventive Actions (CA/PAs), Rev. 0.02, effective 2/5/14, does not require that various sources of quality data be analyzed to identify existing and potential causes of nonconforming products or other recurring quality problems.
- B. There is a lack of a root-cause investigation into returned ED-530XT duodenoscopes with a recurring Distal End Cap failure.

| Work Order/RMA No. | Serial No. | Repair Date |
|--------------------|------------|-------------|
| RP1310160003@@1 | 2D102A092 | 10/31/13 |

AMENDMENT 1

| | | |
|---------------------------------|--|---------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE Li Li, Investigator | DATE ISSUED 04/20/2015 |
| |  | |

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

| | |
|---|---|
| DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry | DATE(S) OF INSPECTION 03/24/2015 - 04/09/2015* |
| | FEI NUMBER 2431293 |

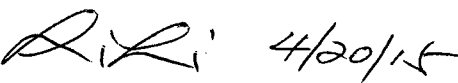
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Keiichi Nagata, President

| | |
|--|---|
| FIRM NAME Fujifilm Medical Systems U.S.A., Inc. | STREET ADDRESS 10 Highpoint Drive |
| CITY, STATE, ZIP CODE, COUNTRY Wayne, NJ 07470-7431 | TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer |

| | | |
|-----------------|-----------|----------|
| RP1307310005@@1 | 1D102A012 | 12/8/13 |
| RP1308050040@@2 | ND102A013 | 12/16/13 |
| RP1405280024@@1 | AD102A042 | 8/18/14 |
| RP1409270021@@1 | 2D102A074 | 11/21/14 |
| RP1410280037@@1 | 1D102A060 | 12/2/14 |
| RP1412100005@@1 | 5D102A546 | 1/23/15 |
| RP1502180030@@1 | ND102A023 | 3/13/15 |

- C. There is a lack of a root-cause investigation into returned ED-530XT duodenoscopes with a recurring image failure and a water leak.
- Work Order, RMA No. RP1406180059@@1, closed 7/16/14, indicates that the unit, Serial No. 4D102A020, had a blurry image and some water was inside the camera.
 - Work Order, RMA No. RP1409040027@@1, closed 12/24/14, indicates that the camera of the unit, Serial No. ND102A239, was hazy and out of focus, and the window glass was leaking.
 - Work Order, RMA No. RP1409170041@@1, closed 1/16/15, indicates that the unit, Serial No. ND102A222, had a red color image and there were bubbles at the tip.
 - Work Order, RMA No. RP1502040013@@1, closed 2/19/15, indicates that the unit, Serial No. 5D102A510, had lines in the image and there was fluid inside Camera Head Assembly (CHA) and Operating Section Assembly (OSA).
- D. There is a lack of a root-cause investigation into returned ED-530XT duodenoscopes with recurring peeled surface components.
- Work Order, RMA No. RP1310240046@@1, closed 12/14/13, indicates that the unit, Serial No. 5D102A004, had a peeled tube of Flexible Section Main for Light Guide Bundle (FSM).
 - Work Order, RMA No. RP1410280037@@1, closed 12/2/14, indicates that the unit, Serial No. 1D102A060, had a peeled FSM.
 - Work Order, RMA No. RP1408250046@@1, closed 12/19/14, indicates that the unit, Serial No. 5D102A509, had a peeled tube of Flexible Section Assembly (FSA).
 - Work Order, RMA No. RP1503020017@@1, closed 3/18/15, indicates that the unit, Serial No. AD102A039, had a peeled FSM.
- E. There is a lack of corrective actions for returned ED-530XT duodenoscopes with component failures which the firm rooted as normal wear and tear.
- Complaint No. 11831, dated 4/4/11, and Work Order RMA No. 2196064, dated 4/1/11, indicates that water was not cleaning the lens of Serial No. 5D102A020 during a medical procedure and the one year old Air/Water Nozzle was partially clogged.
 - Complaint No. 11610, dated 11/10/11, and Work Order RMA No. 2183980, dated 9/30/10, indicates that Serial No. 4D102A053 looped in a patient's stomach, and the FSA was 15 months old with an insertion tube that was too flexible.
 - Complaint No. 12460, dated 9/26/13, and Work Order RMA No. 2224462, dated 3/29/13, indicates that the

AMENDMENT 1

| | | |
|---------------------------------|--|---------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE Li Li, Investigator | DATE ISSUED 04/20/2015 |
| |  | |

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

| | |
|--|---|
| DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry | DATE(S) OF INSPECTION 03/24/2015 - 04/09/2015* |
| | FEI NUMBER 2431293 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Keiichi Nagata, President

| | |
|--|---|
| FIRM NAME Fujifilm Medical Systems U.S.A., Inc. | STREET ADDRESS 10 Highpoint Drive |
| CITY, STATE, ZIP CODE, COUNTRY Wayne, NJ 07470-7431 | TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer |

- d. approximately 2 year old elevator and wire caused a stent to have a tight clearance at the elevator tip. Complaint No. 12658, dated 10/28/13, and Work Order RMA No. 2234449, dated 8/20/13, indicates that the complainant could not push a biliary stent through Serial No. 2D102A020 due to a kinked 1.5 years old Forcep Channel Tube (FCT).
- e. Complaint No. 12913, dated 12/24/14, and Work Order RMA No. RP1408250045@@1, dated 10/1/14, indicates that the 4 year old Air/Water Cylinders of Serial No. 5D102A510 and 5D102A509 caused a water leak over the CHA lens.

OBSERVATION 4

A correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA.

Specifically,

- A. Complaint No. 12267, received 3/26/12, indicates that the suction button of ED530XT Duodenoscope, Serial No. ND102A039, became lodged in the endoscope during a medical procedure, causing a 20 minute delay in completing the procedure. Complaint No. 12403, received 10/11/12, indicates that the suction button stuck several times during the medical procedure. Both complaint reports indicate that a contrast agent dried on the surface of the suction button and caused the button to get stuck during the procedure. As a corrective action, a Technical Service Communication (TSC) letter was released in April 2004 2014 to the firm's field sales and service representatives for informing the customers of the need for preparing a syringe filled with sterile water for the medical procedure. The syringe is used for releasing the suction button with water if it gets stuck during the procedure. The firm has not submitted a field correction report since the release of the TSC letter.
- B. **Complaint Corrective Action** No. 12468, received 1/14/13, indicates that ED530XT Duodenoscope, Serial No. ND102A208, ND102A209, ND102A210, and ND102A211 were not compatible with EPX-2500 Processor, as the duodenoscopes had an incorrect mask size for the processor. On 4/11/14, the firm sent a letter to a customer site and informed the site that its ED530XT Duodenoscope, Serial No. 5D102A019, is not operationally compatible with the EPX-2500 processor, and there is a possibility of an improper image display (aspect ratio / resolution) when the equipment combination is used. The firm also offered to upgrade the EPX-2500 processor with the compatible processor, EPX-4400. The firm has not submitted a field correction and removal report since 4/11/14.

Production and Process Controls

AMENDMENT 1

| | | |
|---------------------------------|--|---------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE Li Li, Investigator | DATE ISSUED 04/20/2015 |
| | <i>Li Li 4/20/15</i> | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054
(973) 331-4900 Fax: (973) 331-4969
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

03/24/2015 - 04/09/2015*

FEI NUMBER

2431293

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Keiichi Nagata, President

FIRM NAME

Fujifilm Medical Systems U.S.A., Inc.

STREET ADDRESS

10 Highpoint Drive

CITY, STATE, ZIP CODE, COUNTRY

Wayne, NJ 07470-7431

TYPE ESTABLISHMENT INSPECTED

Medical Device Manufacturer

OBSERVATION 5

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

Specifically, Complaint No. 12845, closed 11/3/14, indicates that two patients had a medical procedure using ED530XT Duodenoscopes, Serial No. ND102A125 and 1D102A045, were tested positive for carbapenam-resistant enterobacteriaceae (CRE). Both duodenoscopes were also tested positive for CRE. The complaint report indicates that the firm conducted a site visit and revealed that the customer used a manual cleaning and an automated cleaning process for reprocessing the duodenoscopes, and did not adhere to the firm's reprocessing instructions for the manual cleaning, and lacked a confirmation from the cleaning equipment manufacturer for the automated cleaning for adequacy. There is a lack of user reprocessing validation studies to ensure that the firm's duodenoscope reprocessing instructions are adequate for its intended uses.

AMENDMENT 1

EMPLOYEE(S) SIGNATURE

Li Li, Investigator

DATE ISSUED

04/20/2015

SEE REVERSE
OF THIS PAGE

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

| | |
|--|--|
| <small>DISTRICT ADDRESS AND PHONE NUMBER</small> 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry | <small>DATE(S) OF INSPECTION</small> 03/24/2015 - 04/09/2015* |
| | <small>FEI NUMBER</small> 2431293 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Keiichi Nagata, President

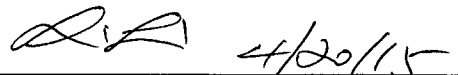
| | |
|---|--|
| <small>FIRM NAME</small> Fujifilm Medical Systems U.S.A., Inc. | <small>STREET ADDRESS</small> 10 Highpoint Drive |
| <small>CITY, STATE, ZIP CODE, COUNTRY</small> Wayne, NJ 07470-7431 | <small>TYPE ESTABLISHMENT INSPECTED</small> Medical Device Manufacturer |

Observation Annotations

- | | |
|-------------------------------------|-------------------------------------|
| Observation 1: Promised to correct. | Observation 2: Promised to correct. |
| Observation 3: Under consideration. | Observation 4: Promised to correct. |
| Observation 5: Promised to correct. | |

*** DATES OF INSPECTION:**
 03/24/2015(Tue), 03/25/2015(Wed), 03/30/2015(Mon), 04/01/2015(Wed), 04/02/2015(Thu), 04/09/2015(Thu)

AMENDMENT 1

| | | | |
|---------------------------------|---|--|--|
| SEE REVERSE OF THIS PAGE | <small>EMPLOYEE(S) SIGNATURE</small> Li Li, Investigator |  | <small>DATE ISSUED</small> 04/20/2015 |
| | | | |