DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Teiichi Goto
Corporate Vice President
General Manager
Medical System Business Division
Fujifilm Corporation
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Kanagawa 258-8538 Japan

AUG 12 2015

Document Number: EC150232/E001

Dear Mr. Goto:

It has come to our attention that you are currently marketing and servicing the ED-530XT duodenoscope in the United States. The ED-530XT duodenoscope is intended for endoscopic diagnosis, treatment and video observation and meets the definition of a device as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

During an inspection of your facility dated March 24, 2015 through April 9, 2015,Food and Drug Administration (FDA) investigators noted that in a letter-to-file (LTF) dated November 8, 2005, your firm indicated its determination that the ED-530XT duodenoscope was cleared for distribution under K042076 (the 510(k) clearance number for the ED-450XT5 duodenoscope) because the ED-530XT duodenoscope contained the same material composition and intended use as the ED-450XT5 duodenoscope.

However, we have reviewed your firm's November 8, 2005 LTF and determined that there are significant differences between the ED-450XT5 and the ED-530XT duodenoscopes. Significant changes include, but are not limited to:

- Position of image and the redesign of the air/water nozzle;
- Lens;
- Charged couple device (CCD) and instrument channel at the distal tip;
- Elevator mechanism; and
- Materials of the distal end cap.

We have determined that a new 510(k) submission is required for the ED-530XT duodenoscope.

Mr. Teiichi Goto
Fujifilm Medical Systems U.S.A., Inc.

On July 9, 2015, FDA held a teleconference to discuss your firm's November 8, 2005 LTF. Your firm agreed to submit a 510(k) premarket notification for the ED-530XT duodenoscope. We received your 510(k) for the ED-530XT duodenoscope on August 10, 2015.

In the July 9, 2015 teleconference, FDA requested information on additional models that your firm determined were cleared and distributed in the United States under other LTFs. Your firm agreed to provide the 2002 and 2003 LTFs that introduced the 250 and 450 duodenoscope series under K042076 (the 510(k) clearance number for the ED-450XT5 duodenoscope). We acknowledge that on July 20, 2015, your firm submitted the LTFs for the 250 and 450 duodenoscope series.

We have assessed the LTFs for the ED-250XT5, ED-450XT5, ED-250XL5, and ED-450XL5 duodenoscopes and determined that the modifications did not significantly affect the safety or effectiveness of these devices. Therefore, new 510(k) submissions are not required at this time for these duodenoscopes.

Additionally, we requested that your firm identify any other older models that are still in the field. Your firm stated that it is in the process of identifying whether any older open-channel duodenoscopes are currently used in the field. You also provided a field correction plan for older open-channel duodenoscopes and indicated that no additional devices were marketed in the United States, other than the list of duodenoscope models previously provided to the agency.

We have assigned a unique document number that is cited above. Any additional information should reference this document number and should be submitted to:

Chief, Surveillance and Enforcement Branch I, WO66-3520
Division of Premarket and Labeling Compliance
Office of Compliance
Center for Devices and
Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993
Attn: Jeene Bailey or LaShanda Long

Mr. Teiichi Goto
Fujifilm Medical Systems U.S.A., Inc.

If you have questions relating to this matter, please feel free to call Jeene Bailey at 301-796-5486, or log onto our web site at www.fda.gov for general information relating to FDA device requirements.

Sincerely yours,

Anastacia M. Bilek, Ph.D.
Director
Division of Premarket and
Labeling Compliance
Center for Devices and
Radiological Health

cc:

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