DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
White Oak Building 66
Silver Spring, MD 20993

Mr. Hiroshi Suzuki
President and CEO
Hoya Corporation (PENTAX Life Care Division)
Showanomori Technology Center
1-1-110 Tsutsujigaoka, Akishima-shi
Tokyo 196-0012
+81-42-500-583

AUG 12 2015

Document Number: EC150252/E001

Dear Mr. Suzuki:

It has come to our attention that you are currently marketing and servicing the ED-3670TK duodenoscope and servicing the ED-3490TK duodenoscope in the United States. The ED-3670TK and ED-3490TK duodenoscopes are intended for endoscopic diagnosis, treatment and video observation and meet the definition of a device as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

ED-3670TK

During an inspection of your facility dated April 13, 2015 through April 21, 2015, Food and Drug Administration (FDA) investigators noted that in a letter-to-file (LTF) titled "Pentax Medical Company Clearance Statement," your firm indicated its determination that the ED-3670TK duodenoscope was cleared for distribution under K963056 (the 510(k) clearance number for the ED-3410 duodenoscope) because the ED-3670TK duodenoscope contained the same intended diagnostic/therapeutic effect (with respect to the indications for procedure), method of introduction, technical characteristics, design, and range of descriptive characteristics as the ED-3410 duodenoscope.

Additionally, in another LTF dated September 4, 2014, your firm reevaluated the ED-3670TK duodenoscope for equivalency to the ED-3490TK duodenoscope (K092710) and determined that a 510(k) submission was still not required for the ED-3670TK duodenoscope.

Prior to our most recent inspection, FDA sent a letter dated July 31, 2013 to your firm's Montvale, New Jersey location regarding the agency's awareness of the marketing of your devices, including the ED-3670TK duodenoscope, and requesting that your firm provide the 510(k) clearance number for this duodenoscope model. Your firm provided

the same LTF comparing the ED-3670TK duodenoscope to the ED-3410 duodenoscope in response.

We have reviewed your firm's LTFs and your May 12, 2015 response to our investigators' observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, and determined that the LTFs do not contain a complete comparison of the new and comparator devices. For example, the only optical characteristics that are included in the LTFs are image transmission via fiber or video, the angle of view, direction of view, and the depth of field. However, your LTFs do not contain discussions, among other things, regarding the resolution, magnification, or any other imaging characteristics.

ED-3490TK

During the inspection dated April 13, 2015 through April 21, 2015, FDA also noted that your firm marketed the ED-3490TK duodenoscope from September–December 2009, prior to receiving 510(k) clearance under K092710 on December 2, 2009. Additionally, we became aware that your firm made several design changes after clearance. In particular, FDA found that the following three modifications to design were made:

- Due to discontinuation of coating agent used to IFT, change in the coating material;
- Due to countermeasure for defect that rubber part of rubber trim collar is peeled off by using disinfectant for reprocessing, change in the rubber material and the shape of metal material; and
- Firmware change for remote control function.

On July 9, 2015, FDA held a teleconference to discuss your firm's LTFs. FDA requested that you provide a more detailed description of these changes and the justification for not submitting a new 510(k) premarket notification for the ED-3490TK duodenoscope. We also requested that your firm provide LTFs for any other duodenoscopes that were marketed and distributed in the United States.

In a letter dated July 13, 2015, you agreed to undertake the following actions:

- Provide a detailed summary of changes for the ED-3490TK duodenoscope model with the corresponding rationale for not submitting a 510(k) premarket notification to FDA by July 24, 2015.
- Identify and summarize the changes to the ED-3670TK compared to its predicate ED-3490TK duodenoscopes, including the rationale for not submitting a new 510(k) premarket notification for each duodenoscope model to be provided to FDA by August 5, 2015.
- Review and revise the June 2014 LTF, regarding the ED-3670 TK which identified the comparison predicate, the ED-3490TK duodenoscope, to provide

more robust descriptions of each change and the rationale for not submitting a new 510(k) premarket notification to be provided to FDA by August 14, 2015.

- Provide FDA with translations of select verification test documentation to support design changes to the ED-3670TK duodenoscope since initial marketing. In your letter, you did not provide an estimated date of completion.

On July 24, 2015, your firm provided FDA with a more detailed description of three changes to the ED-3490TK duodenoscopes and your justification for not submitting a new 510(k) premarket notification. On August 7, 2015, FDA received the requested information on the ED-3670TK.

Your firm also stated that the only duodenoscopes which have been, or are currently marketed in the United States are: ED-3410, ED-3440T, ED-3440, ED-3230, ED-3230K, ED-3430, ED-3430K, ED-3430T, ED-3430TK, ED-3630T, ED-3270K, ED-3470TK, ED-3670TK, and the ED-3490TK duodenoscopes.

Additionally, the ED-3410 duodenoscope was marketed pursuant to a cleared 510(k) submission (K963056) but has not been sold or serviced in the United States since 2009, and the ED-3440T duodenoscope was marketed pursuant to a cleared 510(k) submission (K961568) but has not been sold in the United States since 2003.

We are currently assessing the information that your firm provided on July 24, 2015 for the ED-3490TK duodenoscope. FDA will review the additional information on the other devices upon receipt. If the agency determines that a 510(k) submission is required, we will promptly request that you provide FDA's Office of Device Evaluation with your firm's submission. The kind of information that your firm needs to submit in order to obtain approval or clearance for a device is described on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm.

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. Hiroshi Suzuki
Hoya Corporation (PENTAX Life Care Division)

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

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

cc:

Ganesh Ramaswamy,
Global President of Hoya Corporation
Hoya Corporation (PENTAX Life Care Division)
Showanomori Techology Center
1-1-110 Tsutsujigaoka, Akishima-shi
Tokyo 196-0012, Japan
+81-42-500-583

Mr. Christopher Burton
Pentax Of America, Inc
3 Paragon Drive
Montvale, NJ 07645-1725

Mr. Tomokazu Kishi
Senior General Manager
Hoya Corporation (PENTAX Life Care Division)
Showanomori Technology Center
1-1-110 Tsutsujigaoka, Akishima-shi
Tokyo, 196-0012 Japan
+81-42-500-583

Gina Crossetta
Vice President, Regulatory and Quality, Americas
Pentax of America, Inc

Mr. Hiroshi Suzuki
Hoya Corporation (PENTAX Life Care Division)

3 Paragon Drive
Montvale, NJ 07645

Krishna Govindarajan
US Agent
Pentax Of America, Inc
3 Paragon Drive
Montvale, NJ 07645-1725

Mr. Hiroshi Suzuki
c/o Ms. Naomi Shirota
Pentax Medical
2-7-5 Naka-Ochiai, Shinjuku-ku
Tokyo 161-8525
Japan