DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 594-4695 Fax:(301) 594-4715 Industry Information: www.fda.gov/oc/industry	04/13/2015 - 04/21/2015
	FEI NUMBER 3008185830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Tomokazu Kishi, Senior General Manager

FIRM NAME	STREET ADDRESS
Hoya Corporation	1-1-110 Showanomori Tech
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Akishima-shi 1960012, Japan	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 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.

(A) Specifically, Pentax Medical Compatible Reprocessing Systems/Agents labeling document (b)(4) Rev: (states that (b) (4) can be used to sterilize (b)(4) endoscopes.

Final report "DISINFECTION/STERILIZATION VALIDATION OF A REUSABLE DEVICE*** PROTOCOL NO. (b) (4) LABORATORY NUMBER (b) (4) is used to support (b) (4) instructions for use (IFU) for the Pentax ED-3490TK and the ED-3670TK devices. A (b) (4) was used to sterilize devices during this validation.

Your firm did not validate the (b) sterilization process of endoscopes with:

a) (b) (4)
b) (b) (4)
c) (b) (4)

(B) The process validation used to support the (b) sterilization of the ED-3490TK and the ED-3670TK devices is inadequate in that the protocol and raw data associated with final report "DISINFECTION/STERILIZATION VALIDATION OF A REUSABLE DEVICE*** PROTOCOL NO. (b) (4) LABORATORY NUMBER (b) (4) is not documented.

(C) The process validations used to support the cleaning and high level disinfection of the ED-3490TK and the ED-3670TK devices are inadequate in that they do not adequately document the testing conditions. Throughout the protocol there is

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mention of (b) (4)
For example, Page 12, step *(b)* of the protocol (Protocol NO. (b) (4)) states to *(b)(4)* *(b)(4)* The supplies list on page 5 indicates the use of "sterile syringes," no size is given.

(D) The process validations used to support the cleaning validations are inadequate in that they do not validate the cleaning of a device with the application of *(b)(4)* . Operation IFUs for the ED-3670TK and ED-3490TK devices include instructions for (b) (4) Cleaning validations for these devices did not include the use of silicone oil.

OBSERVATION 2

Design validation did not ensure the device conforms to defined user needs and intended uses.

(A) Specifically, validation of the ED-3670TK is inadequate in that it did not ensure that the cleaning, high level disinfection, and sterilization IFUs were validated.

Final report "***PROTOCOL NO. (b) (4) LABORATORY NO. (b) (4) used to support (b) (4) IFU for the ED-3670TK device was executed 03/05/1997 using endoscope models: EC-3800TL, EC-3840TL, FD-34X and ED-3440T. A statement of equivalency for these models and the ED-3670TK was not documented before distribution of the device on 01/14/2004.

Protocol NO. (b) (4) used to support the cleaning and high level disinfection IFUs for the ED-3670TK was executed 09/24/2003 using endoscope model ED-3630T. A statement of equivalency for this model and the ED-3670TK was not documented before distribution of the device on 01/14/2004.

(B) Specifically, validation of the ED-3490TK is inadequate in that it did not validate that the cleaning IFUs are representative of the cleaning methods used in the validation.

For example, Protocol NO. (b) (4) is used to validate the cleaning process of the ED-3490TK. Page *(b* step *(b)* of the protocol states (b) (4) A (b) (4) or greater is not established in the IFU.

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OBSERVATION 3

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

(A) Specifically, validation protocol (b) (4) is used to support the cleaning IFUs for the ED-3670TK and the ED-3490TK devices. Your firm has not documented that the simulated use conditions (b) (4) executed in the cleaning validation protocol are representative of actual or simulated use conditions.

(B) The operation IFUs for the ED-3670TK and ED-3490TK devices include instructions for the application of (b) (4). Cleaning validations for these devices did not include the use of (b) (4)

OBSERVATION 4

Design verification does not confirm that design output meets design input requirements.

Specifically, we found that your firm did not adequately ensure that design output met design input requirements for the ED-3490TK at the time of the initial design process. The ED-3490TK models are currently being distributed. You could not provide evidence that output requirements for the following input requirements for the ED-3490TK were met:

a. Line item (b) (4) (b) (4)

b. Line item (b) (4) (b) (4) from the "Risk Management Checklist" (Document number (b) (4) which you have identified as your design input document.

OBSERVATION 5

Procedures for design change have not been adequately established.

Specifically, we found that your design change procedure, *Design Change Control Procedure* (Document Number, (b) (4) is inadequate in that we found that your firm could not provide documentation to show that changes to the marketing material have been evaluated for impact to the design of the ED-3490TK and ED-3670TK models of duodenoscopes. For

example, you changed the marketing brochure, *PENTAX Medical Compatible Reprocessing Systems/Agents*, Document Number (b) (4) Revision f to *PENTAX Medical Compatible Reprocessing Systems/Agents,* Document Number (b) (4) Revision (. However, your firm could not provide documentation to show that Revision (b was evaluated prior to distributing it to customers who use the 3490TK and ED-3670TK models of duodenoscopes.

OBSERVATION 6

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

Specifically, your firm initiated CAPA (b) (4) on 08/22/2012 in response to CAR (b) (4) (initiated on 06/22/12). Your firm received (complaints during 2007-August 2012 relating to mechanical obstructions lodged in the channel of a scope that were later dislodged after reprocessing and manual cleaning. These complaints include MDR 2518897-2012-00009. As a corrective action, your firm updated "Risk Management File (b) (4) [Production and Post-Production Information]" to include a hazard of user error with the following cause: *(b)(4)*

(b)(4) ." Your risk evaluation concluded this hazard has a severity level of (b) (4) and a probability of (b) (4) Additionally as a corrective action, service note (b) (4) was implemented on 09/06/2013 for the use of a ball probe inspection tool to be used on scopes received for repair/servicing to detect foreign material. This CAPA was closed as effective on 10/31/2014.

CAPA (b) (4) is inadequate in that your corrective actions did not address mechanical obstructions lodged in the channel of the scope observed by the user after reprocessing and manual cleaning. During your review of the effectiveness of the corrective actions implemented (4/2014 -9/2014), your firm filed 3 MDRs (2518809-2014-00006 filed 05/02/2014, 2518897-2014-00008 filed 07/25/2014, and 2518897-2014-00009 filed 08/25/2014) related to complaints of mechanical obstructions lodged in the channel of a scope.

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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.

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