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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 10903 New Hampshire Avenue<br>Silver Spring, MD 20993<br>(301) 594-4695 Fax:(301) 594-4715<br>Industry Information: www.fda.gov/oc/industry | 04/22/2015 - 04/24/2015<br>FEI NUMBER<br>3003782610 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Ryosuke Akagi, General Manager

| FIRM NAME | STREET ADDRESS |
|---|---|
| Hoya Corporation Pentax Life Care Division, Miyagi Factory | 30-2 Okada, Aza-Shimomiyano, Tsukidate Tsukidate, |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Kurihara-shi, Miyagi 9872203, 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 validated according to established procedures.

Specifically,

A. Your firm has not validated approximately (b) software processes used in the manufacturing /testing of finished devices. Example processes include the following:

- (b)(4), Version (b) implemented August 2008
- (b)(4), Version (b) implemented January 2009
- (b)(4), implemented June 2004

B. The process parameters/test methods for the following processes used in the manufacture/inspection of the ED-3490TK, a class II medical device have not been validated

a. (b) (4)

b. (b) (4)

C. We found that your firm failed to validate the process referred to as the (b) (4) which is a process step for the 3490TK model of duodenoscopes. The process involves applying the (b) (4)

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|---|---|---|
| | Linda Linh T. Nguyen, Investigator<br>Nicole S. Williams, Investigator | 04/24/2015 |

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## OBSERVATION 2

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

Specifically,

A. CAPA (b) (4) opened on 11/17/2013 identified corrective actions to your firm's software validation procedure and identified (b) software processes used in your firm's manufacturing or quality system management processes that required validation activities. CAPA (b) (4) was closed as effective on 04/15/2015 before the completion of validation activities for (b) of the identified software processes requiring validation.

B. CAPA procedure (b) (4) is inadequate in that the established data trending procedure (b) (4) does not adequately outline statistical methods used to detect recurring quality problems.

## OBSERVATION 3

The device history record does not demonstrate that the device was manufactured in accordance with the device master record.

Specifically, device history records for the ED-3490TK device are inadequate in that they do not include or reference all acceptance records which demonstrate that the device was manufactured in accordance with the DMR. For example, step (b) of the (b) (4) assembly instructions (b) (4)

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## Observation Annotations

Observation 1: Promised to correct.
Observation 2: Promised to correct.
Observation 3: Promised to correct.

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