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, 20993 (301)594-4695 Fax:(301)594-4715	3/14/2016-3/17/2016
	FEI NUMBER 3003713161

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Katsushige Nakamura , President

FIRM NAME	STREET ADDRESS
Mitaka Kohki Co., Ltd.	1-18-8 Nozaki
CITY, STATE, ZIP CODE, COUNTRY Mitaka-Shi, Tokyo, 1810014 ,Japan	TYPE ESTABLISHMENT INSPECTED

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:

OBSERVATION 1

Procedures for design control have not been established.

Specifically, the first revision of the firm's Design Development Procedure, Chapter 7.3 of the Quality Manual (b)(4) was established on 8/1/13. The current revision of the Design Development Procedure, Chapter 7.3 of the Quality Manual (b)(4) was established on 12/25/13. The firm has yet to subject the POINT SETTER – Model PSMS-2 (cleared under 510(k) #K984355 on 4/1/99 for General Surgery and 510(k) #K991989 on 8/27/99 for Neuro Surgery) through the design control process in order to ensure that specified design requirements are met. The firm has been shipping this product to the (b)(4)

OBSERVATION 2

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

Specifically, the firm's Improvement (Corrective Actions) Procedure, Chapter (b)(4) of the Quality Manual (b)(4) states that contentious suitability and validity of the quality management system through the quality policy, quality targets, audit result, data analysis, corrective and preventive actions and management reviews, and clarify any necessary changes to maintain the system to make actions.

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	Thai T Duong, Investigator ☐ Invalid signature X Thai T Duong Thai T Duong Investigator Signed by: Thai T. Duong -S	3/17/2016

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However, the firm has yet to identify the quality data sources to be analyzed, using the appropriate statistical methodology where necessary, to detect recurring quality problems. Also, no data analysis has been performed and no CAPA has been initiated.

OBSERVATION 3

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

Specifically, the firm's Customer Complaint Procedure, Section (b)(4) of the Quality Manual (b)(4) (b)(4) is incomplete in that:

a) It fails to ensure that all complaints are processed in a uniform and timely manner;
b) It fails to ensure that Oral complaints are documented upon receipt;
c) It fails to ensure that complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR Part 803;

For example, the firm failed to document the following complaints (hence, no complaint files):

MDR Report #9035807-2007-31 (dated 11/29/07) – A week after a Neuro procedure, the hospital asked us to evaluate the subject arm; hospital alleged that during the Neuro procedure, there was spontaneous movement of the Mikaka arm which was holding a scope that had been introduced into the patient. Hospital alleges that patient received injury due to this movement…

Point Setter Defective Axis- 1 &2 Spring Report – An email (reportedly) received from Mitaka USA stating "Some Point Setters do not have sufficient holding power." This resulted in a recall of the Mitaka Point Setters in April of 2009.

OBSERVATION 4

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Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

Specifically, the firm's Purchasing Procedure, Chapter 7.4 of the Quality Manual (b)(4) Revision (b)(4) states that this procedure is to ensure that the suppliers (procurement sources or outsources) are capable of providing products conforming to the company's requirements.

However, the firm has yet to evaluate the following approved part suppliers (for the POINT SETTER 2Kg):

Name of Supplier	Product
(b)(4)	Compress Spring
	45° Elbow
	Stainless Steel Spacer

OBSERVATION 5

The device history record does not demonstrate that the device was manufactured in accordance with the device master record and 21 CFR 820.

Specifically, the firm's Standard Assembly Manual for the POINT SETTER – Model PSMS-2 is incomplete in that the assembly instructions require the following:

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Document #	Assembly Procedure
(b)(4)	1 - Altazimuth Brake Assembly
	2 - Altazimuth Assembly
	3 - Attaching a Hose on the Air Switch
	4 - Assembly of Top Ball Joint
	5 - Assembly of Lock-Knob
	5.1 - Assembly of Holder Fixing Part
	6 - Assembly of Grip Unit
	7 - Assembly of Balls
	8 - Assembly of Ball Joints
	9 - Assembly of Air Inlet Fitting
	10 - Connecting Unit and Altazimuth Mount
	11 - Attaching Labels

However, it does not require the technician(s) to document the operation/assembly steps in the production record (showing that they were performed). For example: DHRs for Serial (b)(4) Serial (b)(4) and Serial (b)(4)

This was also confirmed during the walk-thru of the facility on 3/14/16. Five (reportedly) completed Pointer Setters and (b)(4) (reportedly) completed Table Adapters were observed in the manufacturing area (on the first floor of the facility) with no identification and no documentation.

OBSERVATION 6
Procedures to ensure equipment is routinely calibrated have not been established.

Specifically, the following spring scale/balancer equipment (used as part of the final device testing/acceptance of the POINT SETTER – Model PSMS-2) was found not calibrated (to national or international standards) during the walk-thru of the facility on 3/15/16:

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Equipment	Manufacturer	Unit ID #
(b)(4)		

OBSERVATION 7
Procedures for device history records have not been established.

Specifically, the firm has yet to establish a Device History Record (DHR) procedure. In addition, eleven DHRs from 1/2015 to 3/2016 (pertaining to the POINT SETTER – Model PSMS-2) were selected for review during the inspection. None of the DHRs included or referred to the location of the primary identification label and labeling used for each production unit. For example: DHR for Serial (b)(4) (Pointer Setter) with Serial (b)(4) (Table Adapter); DHR Serial (b)(4) (Pointer Setter) with Serial (b)(4) (Table Adapter); and Serial # (b)(4) (Pointer Setter) with Serial (b)(4) Table Adapter).

OBSERVATION 8
Written MDR procedures have not been developed.

Specifically, the firm has yet to establish a Medical Device Reporting procedure.

Annotations to Observations

Observation 1:	Promised to correct within 4 Weeks
Observation 2:	Promised to correct within 8 Weeks
Observation 3:	Promised to correct within 8 Weeks
Observation 4:	Promised to correct within 4 Weeks
Observation 5:	Promised to correct within 12 Weeks
Observation 6:	Promised to correct within 8 Weeks
Observation 7:	Promised to correct within 12 Weeks

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Observation 8: Promised to correct within 8 Weeks

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