DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Attn: Thomas Slater CDRH, White Oak Bldg. 66, Rm 3540 10903 New Hampshire Ave Silver Spring, MD USA 20993 Industry Information: www.fda.gov/oc/industry	9/5 - 8/2016
	FEI NUMBER 3012789229 ADE

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mitsuko Narishige, CEO

FIRM NAME	STREET ADDRESS
Narishige Co. Ltd.	13-12, Kyuden 3 Chome
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Setagaya-ku, Tokyo, 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 (I) (WE) OBSERVED:

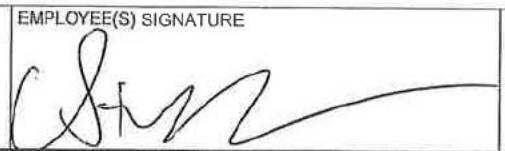
1. The Design Control Procedure (b) (4) does not describe that design validation would validate the design intended use and user requirements. The design control procedure section regarding design change does not describe that design changes will be validated or where appropriate verified. The procedure includes a section regarding (b) (4). The section on (b) (4) does not sufficiently define when this section of the procedure will be used to ensure that design changes will be verified.

2. The Design History file for the IM-11 Pneumatic micro injector did not include verification that the design output met the design input. Design validation did not include an acceptance criteria for the user evaluations that were made. The Design History file for the IM HD1 micro manipulator included design inputs (b) (4) (b) (4) (b) (4). The firm did not have documentation to verify that the design output met the design input.

3. The "Common Test Procedure for Oil Hydraulic Manipulator" is not a controlled procedure according to the firm's Document Control Procedure (b) (4) There is no record of the approval of the "Common Test Procedure for Oil Hydraulic Manipulator" by a designated individual.

4. Procedure (b) (4) for Incoming Testing does not describe the quantity of the incoming product that will be tested and what testing will be made. Incoming records such as (b) (4) do not show the number of the goods tested or what testing was made. (received on 28.7.28) ADE (9/8/2016)

5. Supplier Control Procedure (b) (4) has not been effectively implemented. Routine evaluation of the non conformance from the supplier (b) (4) has not been completed as per the procedure. The procedure describes evaluation of non conformance from incoming receipt from the supplier. Non conformance is (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Stephen D. Eich, Investigator	09/08/2016

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(b) (4) (b) (4) and this non conformance is not included in the supplier evaluation.

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		Stephen D. Eich, Investigator	09/08/2016