DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	6/5/2017-6/6/2017
	FEI NUMBER 3009761435

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Jason Hartnett , Quality Assurance & Regulatory Affairs Manager

FIRM NAME	STREET ADDRESS
Aero Data Metal Crafters Inc	2085 5th Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ronkonkoma, NY 11779-6903	Medical 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 OBSERVED:

OBSERVATION 1

Written MDR procedures have not been developed, maintained and implemented.

Specifically, your firm has not written and established an appropriate Medical Device Reporting procedure. As such, you do not have an MDR for your Mammography Positioning Chair Model MPC1000-E which is a Class I Medical Device.

OBSERVATION 2

A device history record has not been adequately maintained.

Specifically,

a) Your firm does not keep paper or scanned copies of the signed and reviewed Device History Records for the Mammography Positioning Chair Model MPC100-E to demonstrate that the device is manufactured in accordance to the Device Master Record.
b) Your firm does not retain the Device History Records for a period time equivalent to the design and expected lifecycle of the device for the Mammography Positioning Chair Model MPC100-E.
c) Your firm does not maintain record of serialized label and other labeling affixed to the Mammography Positioning Chair Model MPC100-E.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jose O Hernandez, Investigator	Verifying... X Jose O Hernandez Jose O Hernandez Investigator Signed by: Jose O. Hernandez-guzman -S	6/6/2017

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OBSERVATION 3

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

Specifically, your firm's complaint procedure found under SOP16.2- Customer Complaints, revision A with effective date: 6/29/12 does not specify the procedure for the receiving, reviewing, documentation and the timely evaluation of complaints to determine if in-depth investigation and corrective actions are required the Mammography Positioning Chair MPC1000-E which is a Class I Medical Device.

OBSERVATION 4

Corrective and preventive action activities and/or results have not been documented.

Specifically, your firm failed to document the CAPA process and follow up investigation for rejection report number (b) (4) received as part of a complaint in 01/08/2016 for the column guides of the Mammography Positioning Chair MPC1000-E., were changes were made to Form 5517- Mammography Positioning Chair Inspection Report, Revision A.

Annotations to Observations

Observation 1: Promised to correct
Observation 2: Promised to correct
Observation 3: Promised to correct
Observation 4: Promised to correct

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Jose O Hernandez, Investigator

Verifying...
X Jose O Hernandez
Jose O Hernandez
Investigator
Signed by: Jose O. Hernandez-guzman -S

DATE ISSUED
6/6/2017