DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	7/10/2017-7/12/2017 FEI NUMBER 1000111140

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Clifford E. Gammons , President

FIRM NAME	STREET ADDRESS
Adroit Medical Systems Inc	1146 Carding Machine Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Loudon, TN 37774-5650	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

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

Specifically,

Your firm's device history record does not indicate that the production of your Class II heat therapy pump (HTP-1500) medical device was manufactured according to the device master record. Currently, the device history records only consist of the "Pump Test Data Sheet" and a shipping invoice identifying each pump's unique serial number. For example, the device history record does not identify the component materials used in the manufacturing of the pump.

OBSERVATION 2

Procedures for device history records have not been adequately established.

Specifically,

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	Matthew R Mcnew, Investigator	X	7/12/2017

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You have not established a device history record (DHR) procedure in order to maintain your device history records. For example, a DHR procedure has not been implemented for the Heat Therapy Pump-1500, a Class II medical device.

In section 4.2 of your Quality Manual procedure, it states (b) (4) [redacted]".

Annotations to Observations

Observation 1: Not annotated
Observation 2: Not annotated

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	Matthew R Mcnew, Investigator	X	7/12/2017