

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

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 03/08/2010 - 03/09/2010
	FEI NUMBER 3004577174

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Aaron (NMI) Behar, Vice President of Sales

FIRM NAME ARJ Medical, Inc.	STREET ADDRESS 209 State St E
CITY, STATE, ZIP CODE, COUNTRY Oldsmar, FL 34677-3654	TYPE ESTABLISHMENT INSPECTED Specifications Developer, Initial Importer/Distributor

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
 The quality policy and objectives were not established.
 Further, you have not established quality system procedures.

OBSERVATION 2
 The procedures for implementing corrective and preventive actions were not established.

OBSERVATION 3
 Complaint handling procedures for receiving, reviewing, and evaluating complaints have not been established.

OBSERVATION 4
 Complete complaint files are not maintained.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Joshua J. Silvestri, Investigator Melinda B. Lewis, Investigator	DATE ISSUED 03/09/2010
		

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OBSERVATION 5


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

OBSERVATION 6

Procedures to control the design process of the device were not established.
 Specifically, you have not established design procedures or records covering the Accutest® URS - 10 Urine Reagent Strip.

OBSERVATION 7

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

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Observation Annotations

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| Observation 1: Promised to correct. | Observation 2: Promised to correct. |
| Observation 3: Promised to correct. | Observation 4: Promised to correct. |
| Observation 5: Promised to correct. | Observation 6: Promised to correct. |
| Observation 7: Promised to correct. | |

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