DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderly Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	7/12/2016-7/14/2016
	FEI NUMBER 3005384855

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jane E. Perrone , Vice President of U.S. Operations

FIRM NAME	STREET ADDRESS
Audifon-USA, Inc.	403 Chairman Court, Suite 1
CITY, STATE, ZIP CODE, COUNTRY Debary, FL 32713-4842	TYPE ESTABLISHMENT INSPECTED 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

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

Specifically, your firm's complaint handling procedures, covered under your "Process Documentation - SOP customer complaints" (Version 3.0 dated 01/09/2015) procedure and "Product Documentation Work Instruction Complaint" (Version 1.0 dated 01/08/2014) work instruction, are inadequate in that:

a) There is no requirement that all complaints be evaluated to determine if they represent an event that must be reported under 21 CFR 803.

b) The procedure and work instruction do not include the definition of a "complaint" as described in 21 CFR 820.3(b) to aid in identification of complaints.

c) There are no provisions to ensure that returned devices handled as "repairs" are evaluated to determine if they should be classified as complaints.

d) There are no provisions to describe requirements for a complaint investigation including identification of most likely underlying cause.

Additionally,

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lisa A Warner, Investigator 7/14/2016 X Lisa A Warner Lisa A Warner Investigator Signed by: Lisa A. Warner -S	7/14/2016

7/14/16

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e) There is no MDR evaluation documented for Complaint #439 received on or around 03/24/2016 due to an oversized shell alleged to have caused a sore on a user's ear.

OBSERVATION 2

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

Specifically,

a) Your firm's "Process Documentation - SOP CAPA" (Version 2.1 dated 01/09/2015) is inadequate in that it lacks the requirement that corrective and preventive actions be verified and/or validated prior to implementation.

b) Your firm's "Process instruction Data Analysis" (Version 2.0 dated 12/14/2015) procedure identifies "key indicators" (quality data) which will be submitted to management (b) (4) for (b) (4) review. The quality data inputs identified for this data analysis includes "(b) (4) and "(b) (4) only.

OBSERVATION 3

Procedures to ensure equipment is routinely calibrated and maintained have not been established.

Specifically, your firm does not maintain procedures for calibration and maintenance of the (b) (4) (b) (4) and the (b) (4) used in (b) (4) activities of shells utilized with ITE devices.

OBSERVATION 4

AMENDMENT 1

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Procedures have not been adequately established to control product that does not conform to specified requirements.

Specifically, your firm's "SOP Handling with non conforming products" (Version 2.0 dated 01/09/2015) is inadequate in that:

a) It does not describe how documentation of non-conforming product occurs, including use of your firm's reject tickets.

b) It does not include provisions for rework in accordance with 21 CFR 820.90(b)(2).

OBSERVATION 5

Written MDR procedures have not been implemented.

Specifically, your firm's "MDR Procedure" (Rev. 001 dated 01/09/2015) is inadequate in that:

a) The procedure does not include provisions to identify and report serious injuries.

b) The procedure does not accurately include provisions to identify reportable malfunctions.

c) The procedure does not address eMDR reporting requirements.

Annotations to Observations

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

AMENDMENT 1

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