DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, 20993 (301)594-4695 Fax:(301)594-4715	10/9/2017-10/12/2017
	FEI NUMBER 3002504821

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Andreas Kurzbuch , General Manager

FIRM NAME	STREET ADDRESS
Maico Diagnostic GmbH	Sickingenstr. 70-71
CITY, STATE, ZIP CODE, COUNTRY Berlin, 10553Germany	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.

a. Specifically, your firm's *Complaint handling and customer feedback* procedure, (b) (4) , dated 09/27/2017 (and previous procedures) does not include:

   (i) The requirement that all complaints are processed in a uniform and timely manner. For example, your firm's September 2017 complaint log shows approximately (b) (4) open/ pending complaints from 2016, and approximately (b) (4) open/ pending from January to August of 2017.

   (ii) The requirement to document whether the device was used for treatment or diagnosis.

   (iii) The requirement to have any unique device identifier (UDI), or universal product code (UPC) used.

b. Complaints involving the possible failure of a device to meet any of its specifications were not reviewed, evaluated and investigated where necessary. For example, a review of (b) (4) complaint files revealed that all complaints were not investigated and any reply to the complainant was not recorded in the files. For example,

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	Roy Baby, Investigator	X Roy Baby Investigator Signed By: 2000351084 Date Signed: 10/12/2017	10/12/2017

(i) Complaint # (b) (4), dated 05/07/2016 for "the right ear is intermittently having a hard time to test" was closed out on 08/30/2017 without any investigation "due to age of issue".

(ii) Complaint # (b) (4), dated 11/16/2016 for "lines on the Display of the device" was closed out on 09/01/2017 without any investigation "due to age of issue".

In addition, service records were not analyzed for possible complaints and did not include a Medical Device Reporting determination. For example,

(i) Service record # (b) (4), dated 04/20/2017 for "wrong measurement" was just treated as a servicing issue and closed out on the same day. An Engineering Change Order ((b) (4)) was necessary to resolve the issue.

(ii) Service record # (b) (4), dated 07/05/2017 for user "can't perform measurement" was just treated as a servicing issue and closed out on the same day. The fault was determined to be material failure and the device was not within specifications.

OBSERVATION 2

Procedures for design review have not been adequately established.

Specifically, your firm's *Design and development* procedure, (b) (4), dated 05/20/2016 was not adequately established to ensure that all design review and meeting minutes were included in the Design History File (DHF) for (b) (4)). In addition, the procedures were not established to ensure that an individual without responsibility for the design stage under review be present. For example, your procedure requires (b) (4)) during several phases of design and development. However, the (b) (4) and the documentation were only made several months after the commercial distribution of the devices.

OBSERVATION 3

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The written MDR Procedure does not include an internal system which provides for the timely and effective identification, communication and evaluation of events that may be subject to medical device reporting requirements.

Specifically, your firm's *Vigilance and MDR* procedure, (b) (4), dated 05/17/2016, does not include the requirements for the timely and effective identification, communication, and evaluations of events that may be subject to MDR requirements; a standardized review process or procedure for determining when an event meets the criteria for reporting; and timely transmission of complete medical device reports. In addition, the procedure does not include definitions for items such as become aware date, serious injury, caused or contributed to, malfunction or supplement or follow-up reports.

Also, the procedure does not include the requirements for (i) information that was evaluated to determine if an event was reportable, and (ii) systems that ensure access to information that facilitates the timely follow-up and inspection by FDA.

In addition, the service records were not analyzed for possible complaints and did not include a Medical Device Reporting determination.

OBSERVATION 4

Procedures for quality audits have not been adequately established.

Your firm did not establish and maintain procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established QSR and to determine the effectiveness of the quality system. The *Audit* procedure, (b) (4), dated 05/03/2016, does not include a requirement that audit criteria cover all applicable portions of 21 CFR 820. For example, the audit plans for 2015 and 2016 did not mention coverage areas including, but not limited to complaints, corrective and preventive actions, training, and servicing. Your firm had an extensive backlog of unresolved complaints and servicing records from 2016-2017.

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Annotations to Observations

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

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