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	10/4/2016-10/5/2016
	FEI NUMBER 3009447557

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Marcelo F. Thomaz , CEO

FIRM NAME	STREET ADDRESS
XZeal Technologies, Inc.	3605 Commerce Blvd Ste G
CITY, STATE, ZIP CODE, COUNTRY Kissimmee, FL 34741-4611	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

Design validation did not ensure the device conforms to defined user needs and intended uses.

Specifically, design validation activities conducted for your Z70 Dental X-Ray device user manual did not ensure that installation instructions included in the user manual were validated for all users that may conduct installation of the device. For example, design validation activities were conducted utilizing only technicians from device distributors and did not include dentists.

OBSERVATION 2

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

Specifically, your firm's "MDR - Mandatory Reporting" procedure (Ver. 02 dated 03/17/2016) is inadequate in that:

a) There are no instructions for conducting a complete investigation of each event and evaluating the cause of the event.

b) It does not describe how your firm will address documentation and record-keeping requirements, including:

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Lisa A Warner, Investigator	X	10/5/2016

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i) Documentation of adverse event related information maintained as MDR event files.
ii) Information that was evaluated to determine if an event was reportable.
iii) Documentation of the deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable.
iv) Systems that ensure access to information that facilitates timely follow-up and inspection by FDA.

Annotations to Observations

Observation 1: Promised to correct
Observation 2: Promised to correct

AMENDMENT 1

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	Lisa A Warner, Investigator	X	10/5/2016