DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	8/11/2017-8/16/2017* FEI NUMBER 3020018

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Patrick S. Jensen , CEO

FIRM NAME	STREET ADDRESS
Cadwell Industries, Inc.	909 N Kellogg St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kennewick, WA 99336-7669	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 corrective and preventive action have not been adequately established.

Specifically, the CAPA planning section of your firm's CAPA System procedure, 823006-000, requires the assignee to "Plan and document how effectiveness of the preventive / corrective action will be verified or validated". For the following two CAPAs the effectiveness plan is not documented:

- CAPA (TT) Defect Number 3217 shows this CAPA was verified to be effective on 8/4/2017, however, there is no documented plan for how the effectiveness should be verified.
- CAPA (TT) Defect Number 3123 shows this CAPA was verified to be effective on 9/2/2016, however, there is no documented plan for how the effectiveness should be verified.

OBSERVATION 2

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

Specifically, your firm's Complaint Handling Processes procedure, 823004-000, requires complaints to be processed in a timely manner. For each of the following three complaints the device indicated in the complaint was returned to your firm over a year ago, however, the devices have not yet been evaluated:

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Stephen R Souza, Investigator	X Stephen R Souza Investigator Signed By: Stephen R. Souza -S Date Signed: 8/16/2017	8/16/2017

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	8/11/2017-8/16/2017*
	FEI NUMBER 3020018

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Patrick S. Jensen , CEO

FIRM NAME	STREET ADDRESS
Cadwell Industries, Inc.	909 N Kellogg St
CITY, STATE, ZIP CODE, COUNTRY Kennewick, WA 99336-7669	TYPE ESTABLISHMENT INSPECTED Manufacturer

- Complaint (Incident) # I000062067 was received by your firm on 2/23/2016. The SRO Work Order Report related to this incident, SRO # SR00509294, shows this device was returned to your firm on 3/3/2016. As of 8/11/2017 this device has not yet been evaluated.
- Complaint (Incident) # I000063676 was received by your firm on 4/19/2016. The SRO Work Order Report related to this incident, SRO # SR00509931, shows this device was returned to your firm on 4/27/2016. As of 8/11/2017 this device has not yet been evaluated.
- Complaint (Incident) # I000065969 was received by your firm on 7/11/2016. The SRO Work Order Report related to this incident, SRO # SR00510793, shows this device was returned to your firm on 7/15/2016. As of 8/11/2017 this device has not yet been evaluated.

OBSERVATION 3

Procedures for design validation have not been established.

Specifically, your firm's Validation Procedure, 826113-000, requires production equivalent devices to be used for clinical validation. The Clinical Validation Test Report for the IOMAX device does not document that production equivalent devices were used for the testing.

Annotations to Observations

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

***DATES OF INSPECTION**

8/11/2017(Fri),8/14/2017(Mon),8/15/2017(Tue),8/16/2017(Wed)

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Stephen R Souza, Investigator	X Stephen R Souza Investigator Signed By: Stephen R. Souza -S Date Signed: 8/16/2017	8/16/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	8/11/2017-8/16/2017*
	FEI NUMBER 3020018

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Patrick S. Jensen , CEO	
FIRM NAME Cadwell Industries, Inc.	STREET ADDRESS 909 N Kellogg St
CITY, STATE, ZIP CODE, COUNTRY Kennewick, WA 99336-7669	TYPE ESTABLISHMENT INSPECTED Manufacturer

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Stephen R Souza, Investigator	X Stephen R Souza Investigator Signed By: Stephen R. Souza -S Date Signed: 8/16/2017	DATE ISSUED 8/16/2017