DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	7/16/2019-7/25/2019* FEI NUMBER 3000145316

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Michael D. Chapman, Technical Manager/ Interim Plant Manager

FIRM NAME	STREET ADDRESS
Highland Industries,Inc.	650 Chesterfield Hwy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cheraw, SC 29520-7005	Contract 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

Process validation activities and results have not been documented and approved.

Specifically, the ozonator generator does not have a completed IQ/OQ and PQ validation records. The lack of an adequate validation resulted in the manufacturing process does not have defined operating parameters and specifications for the ozone levels.

OBSERVATION 2

There is no and inadequate documentation of monitoring and control methods and data, the date performed, the individual performing the process and the major equipment used for a validated process.

Specifically, there are no manufacturing records or test reports for various process validation equipment installation and performance qualification.

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Gamal A Norton, Investigator	X Gamal A Norton Investigator Signed By: Gamal A. Norton -S Date Signed: 07-25-2019 11:36:30	7/25/2019

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Procedures for finished device acceptance have not been established.

Specifically, the firm has not established and maintained procedures for finished device acceptance to ensure the batch of finished devices meet acceptance criteria. The acceptance activities required to meet the device master record specifications are not defined, the associated data and documentation is not reviewed, and there is no documented signature and date authorizing the release of the manufactured devices.

OBSERVATION 4

Sampling plans are not written and based on valid statistical rationale.

Specifically, the firm has not established and maintained valid statistical techniques to ensure that sampling methods are adequate for the intended used.

OBSERVATION 5

The device history record does not demonstrate that the device was manufactured in accordance with the device master record.

Specifically, the firm has not established and maintained adequate procedures to ensure each medical device batch is manufactured in accordance with the device master record specifications.

OBSERVATION 6

Schedules for the adjustment, cleaning, and other maintenance of equipment have not been established.

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Specifically, the firm has not established maintenance schedules for the cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met. The firm does not records of maintenance activities, including the date and individual(s) performing the maintenance activities documented.

OBSERVATION 7

A quality plan has not been established.

Specifically, The firm has not established a quality plan that defines the quality practices, resources, and activities relevant to the medical devices designed and manufactured at this facility. The firm's Quality Manual, No.: CHQM-4.0, Revision: 5 does not acknowledge the 21 CFR 820 requirements that describe and define the establishment of a Quality System for manufacturing medical devices.

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*DATES OF INSPECTION

7/16/2019(Tue), 7/17/2019(Wed), 7/18/2019(Thu), 7/19/2019(Fri), 7/25/2019(Thu)

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Annotations to Observations

Observation 1: Under consideration

Observation 2: Under consideration

Observation 3: Under consideration

Observation 4: Under consideration

Observation 5: Under consideration

Observation 6: Under consideration

Observation 7: Under consideration

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