DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	08/24/2009 - 08/25/2009
	FEI NUMBER 3007291683

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert L. Bolden, President

FIRM NAME	STREET ADDRESS
Clearwater Products, LLC	5910 Pine Hill Rd Ste 9
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Port Richey, FL 34668-6682	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 input requirements that are incomplete were not addressed.

Firm has failed to include as design input that its colonic irrigation system requires 510(k) clearance from FDA and no such 510(k) clearance has been received.

OBSERVATION 2

Adequate quality requirements that must be met by suppliers and contractors were not established, defined, documented, and implemented.

Firm's purchasing control is inadequate in that: All CGMP

(A) Firm has not assured that supplier has completed validation study of extrusion process used to manufacture the [redacted] tubing used in the colonic irrigation system.

(B) There is no documentation that [redacted] tubing meets requirement that it is safe for use with drinking water or it is 'surgical grade' and there is no documentation that [redacted] tubing meets requirement of durometer of [redacted]

(C) Firm's management stated that they require 'table' component received from its supplier to be able to support up to [redacted] however firm has no documentation to verify this requirement is met.

(D) Firm's management has not assured that [redacted] filters provided by firm's supplier meet requirements such as removal of chlorine.

(E) Firm's management has not assured that [redacted] eliminates bacteria and cysts according to the firm's requirement.

(F) Supplier of temperature sensor used in the firm's colonic irrigation system states that the sensor is

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NIST certified in regards to accuracy, but firm has no documentation to verify this statement.

OBSERVATION 3

The design history file was not established or maintained.

Firm has not included in its design history file all design inputs (requirements) of 'table', design verification, design validation of both device and labeling, design review, and risk analysis.

OBSERVATION 4

Procedures for acceptance activities were not documented.

(A) Firm fails to document final inspection of colonic irrigation system including but not limited to the test of the temperature regulating valve.
(B) Incoming inspection of 'table' component of firm's colonic irrigation system including check of its weight and thickness is not documented.

OBSERVATION 5

Quality audits were not conducted to verify that the quality system is effective in fulfilling your quality system objectives.

Firm lacks written internal audit including audit frequency and audit criteria procedure and has completed no internal audits.

OBSERVATION 6

The procedures for implementing corrective and preventive actions were not documented and implemented.

Firm lacks written Corrective and Preventive Action (CAPA) procedure.

OBSERVATION 7

Procedures to control the design process of the device were not documented.

Firm lacks written design control procedure.

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OBSERVATION 8

Written MDR procedures have not been developed and maintained.

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Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Promised to correct within 30 days.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct.
Observation 5:	Promised to correct.	Observation 6:	Promised to correct.
Observation 7:	Promised to correct.	Observation 8:	Promised to correct.

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