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	3/24/2026-3/26/2026
	FEI NUMBER 3000718678

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mary R. Baker, President

FIRM NAME	STREET ADDRESS
Clearwater Colon Hydrotherapy, Inc.	3145 SW 74th Ter
CITY, STATE, ZIP CODE, COUNTRY Ocala, FL 34474-6498	TYPE ESTABLISHMENT INSPECTED 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

The quality management system was not documented in accordance with applicable regulatory requirements.

Specifically, on 03/24/26 I reviewed a copy of the firm's quality procedure manual provided to me by management. The scope of the manual states adherence to 21 CFR 820, with no mention of ISO 13485:2016 without any justification for exclusion. The firm also failed to apply a risk-based approach to the control of appropriate processes needed for the quality system management.

OBSERVATION 2

Records of the results and conclusion of validation of processes and necessary actions from the validation were not maintained.

Specifically, in 2022 your firm began manufacturing medical (b) (4) with the use of an (b) (4) machine. The output of this process is not verified by subsequent monitoring or measuring and must be validated. Management was not able to provide evidence of process validation to demonstrate the ability of the process to achieve planed results consistently.

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Ulysses D Singleton, Investigator X Ulysses D Singleton Investigator Signed By: ULYSSES D. SINGLETON III -S Date Signed: 03-26-2026 13:15:47	3/26/2026

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A design and development file does not adequately include or reference records generated to demonstrate conformity to the requirements for design and development.

Specifically, on 03/26/26 I collected and reviewed your firms Design Control Procedure. I also reviewed the design and development file for the Colonic Irrigation System provided to me by management.. The design and development file contains a list of device components and design specifications Management is not able to provide evidence of the identification of any applicable outputs of risk management, or the stages of design reviews, design verification/validation or design transfer.

OBSERVATION 4

Review of the requirements related to product was not conducted prior to committing to supply product to the customer.

Specifically, on 3/24/26, I asked firm's management if any new processes were implemented since the previous inspection. Mrs. Baker, stated that the firm began manufacturing medical (b) (4) for the Colonic Irrigation System. Management was not able to provide evidence of initial requirements for the new process or evidence that the requirements are being met.

OBSERVATION 5

Documents required by the quality management system have not been adequately controlled.

Specifically, on 03/24/26, I reviewed your firm's document control procedure and found it to be inadequate in that it requires device records to be kept for (b) (4) years or more and not the lifetime of the device. I also noticed that your quality procedure manual contains multiple revisions without a description of the change or the initials of the individual authorizing the approval.

OBSERVATION 6

The re-evaluation of suppliers was not adequately planned.

Specifically, on 3/24/26, I reviewed your firm's documented purchasing procedure. The procedure failed to identify the current frequency of supplier re-evaluation being used by the firm. The procedure also states that

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records of the results of evaluations will be maintained according to section Subpart D 820.40 Document Controls.

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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

Observation 5: Promised to correct

Observation 6: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Ulysses D Singleton, Investigator X Ulysses D Singleton Investigator Signed By: ULYSSES D. SINGLETON III -S Date Signed: 03-26-2026 13:15:47	3/26/2026

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."