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	5/19/2026-5/22/2026
	FEI NUMBER 3029300415

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kenneth A Cherisol, Chief Technology Officer

FIRM NAME	STREET ADDRESS
Bluewave Technologies Inc	1060 E Industrial Dr Ste V
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Orange City, FL 32763-7112	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

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

Specifically:

1. Design and development system records — an approved design and development plan, approved and reviewed design input record, and approved and reviewed design output record for the class 2 BLUEWAVE Disinfection and Deodorization System medical device were not available;
2. Management review — no documented records of reviews conducted were available;
3. Internal audits — no documented internal audit records were available;
4. Risk management — documentation for the class 2 BLUEWAVE Disinfection and Deodorization System medical device reviewed across multiple sources was not consolidated or organized in a manner that allowed for complete review during the inspection;
5. Corrective action — controlled records were not available for two corrective actions related to the class 2 BLUEWAVE Disinfection and Deodorization System medical device;
6. Complaint files CAS-01080-D6R8B4 opened 09/15/2025 and CAS-01076-M2F2S4 opened

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brandon P Thompson, Investigator X Brandon P Thompson Investigator Signed By: Brandon P. Thompson -S Date Signed: 05-22-2026 12:19:25	5/22/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	5/19/2026-5/22/2026
	FEI NUMBER 3029300415

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Kenneth A Cherisol, Chief Technology Officer	
FIRM NAME Bluewave Technologies Inc	STREET ADDRESS 1060 E Industrial Dr Ste V
CITY, STATE, ZIP CODE, COUNTRY Orange City, FL 32763-7112	TYPE ESTABLISHMENT INSPECTED Manufacturer

06/02/2025 for the class 2 BLUEWAVE Disinfection and Deodorization System medical device were not closed despite resolutions having been made.

OBSERVATION 2

The labels of the medical device(s) do not bear a unique device identifier (UDI) that meet the requirements of 801 Subpart B and 21 CFR 830.

Specifically, the class 2 BLUEWAVE Disinfection and Deodorization System medical device does not have a UDI and the device label does not bear one.

OBSERVATION 3

The information required by the Global Unique Device Identification Database for each medical device version or model required to bear a unique device identifier (UDI) was not provided.

Specifically, the class 2 BLUEWAVE Disinfection and Deodorization System medical device does not have a UDI, and no information has been submitted to the Global Unique Device Identification Database (GUDID).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Brandon P Thompson, Investigator	X Brandon P Thompson Investigator Signed By: Brandon P. Thompson -S Date Signed: 05-22-2026 12:19:25	5/22/2026

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	5/19/2026-5/22/2026
	FEI NUMBER 3029300415

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kenneth A Cherisol, Chief Technology Officer

FIRM NAME	STREET ADDRESS
Bluewave Technologies Inc	1060 E Industrial Dr Ste V
CITY, STATE, ZIP CODE, COUNTRY Orange City, FL 32763-7112	TYPE ESTABLISHMENT INSPECTED Manufacturer

Annotations to Observations

Observation 1: Annotation Intentionally Left Blank

Observation 2: Promised to correct

Observation 3: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brandon P Thompson, Investigator X Brandon P Thompson Investigator Signed By: Brandon P. Thompson -S Date Signed: 05-22-2026 12:19:25	5/22/2026

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."