DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	3/30/2026-4/6/2026*
	FEI NUMBER 3007829657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Brent D. Robling, President/CEO

FIRM NAME	STREET ADDRESS
Robling Medical LLC	90 Weathers Ct
CITY, STATE, ZIP CODE, COUNTRY Youngsville, NC 27596-7801	TYPE ESTABLISHMENT INSPECTED Contract Manufactur

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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Corrective actions taken to eliminate the cause of nonconformities to prevent recurrence were unduly delayed.

Specifically, your firm failed to address the corrective and preventive actions identified in CAPA 25-014, CAPA 25-017, and CAPA 25-018 and investigate the root cause within the specified time frames. CAPA 25-013 had a root cause and investigation completion date of 11/21/2025, but there has been no corrective or preventive action plans identified or implemented since that date. The open CAPAs records provided do not show CAPA extension requests being approved for (b) (4) after the planned phase completion dates. Additionally, CAPA 2025-0005 did not follow the time frame requirements outlined in procedure RM-QSP-CP-01, CAPA Process, Revision 02, dated Feb 16, 2026. In the procedure, Step 6.8 states that an Internal ((b) (4) Level) CAPA type will require a (b) (4) investigation due date and (b) (4) implementation date. The CAPA was missed identified and followed a longer time frame allocated for a Low Risk CAPA type.

OBSERVATION 2

One or more processes for risk management in product realization have not been adequately documented.

Specifically, your firm failed to complete your Process Failure Mode and Effects Analysis (PFMEA) for a medical device, the (b) (4) The (b) (4) is a sterile device (b) (4) (b) (4) (b) (4) In the document titled, PFMEA for (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Lashawn M Elam, Investigator Christopher B May, Investigator	X Lashawn M Elam Investigator Signed By: Lashawn M. Elam -S Date Signed: 04-06-2026 11:37:43	4/6/2026

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(b) (4) Packaged (Part (b) (4), Document Number: PFMEA-081 dated 10-18-2024, the PFMEA Spreadsheet does not identify the Potential Patient Effect(s) of Failure or dFMEA Severity for (b) (4) Sterilization.

***DATES OF INSPECTION**
3/30/2026(Mon), 3/31/2026(Tue), 4/01/2026(Wed), 4/02/2026(Thu), 4/06/2026(Mon)

X Christopher B May
Investigator
Signed By: Christopher B. May -S
Date Signed: 04-06-2026 11:38:07

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Lashawn M Elam, Investigator
Christopher B May, Investigator

X Lashawn M Elam
Investigator
Signed By: Lashawn M. Elam -S
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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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Lashawn M Elam, Investigator
Christopher B May, Investigator

X Lashawn M Elam
Investigator
Signed By: Lashawn M. Elam -S
Date Signed: 04-06-2026
11:37:43

DATE ISSUED
4/6/2026

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."