DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	2/26/2026-3/3/2026* FEI NUMBER 3003338236

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Scott W. Bell, President

FIRM NAME	STREET ADDRESS
Tarry Medical Products, Inc.	22 Shelter Rock Ln Unit 36
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Danbury, CT 06810-8268	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

Supplier performance in meeting requirements for the purchased product was not adequately monitored.

Specifically, your firm's purchasing process for Tarry Medical Temperature Probes (models NF-023T and T-08730), Class II medical devices (Product Code FMZ, 21 CFR 880.2910, 510(k) K071977) obtained from contract manufacturer (b) (4) is not adequately established, monitored, and controlled to ensure purchased products conform to specified purchasing requirements. For example:

Your firm's written purchasing agreement with (b) (4) does not adequately specify that no changes to drawing revisions of purchased products should occur without written authorization from Tarry Medical Products, Inc. prior to implementation. However, the contract manufacturer revised the manufacturing print/specification for Tarry Medical Temperature Probes, Model NF-023T, without providing the required notification. Your firm failed to monitor the supplier's performance in meeting this critical purchasing requirement and failed to detect this unauthorized change. This violates the requirement that each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received products and services conform to specified requirements.

Furthermore, your firm failed to address non-fulfillment of purchasing requirements identified during

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Eric C Schmitt, Investigator X Eric C Schmitt Investigator Signed By: ERIC C. SCHMITT -S Date Signed: 03-03-2026 13:33:51	3/3/2026

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(b) (4) audits of (b) (4) conducted on 9/23/2025. These audits revealed that acceptance testing results for Tarry Medical Temperature Probes did not meet specifications. Despite this evidence that the purchased product does not meet specified purchasing requirements, your firm failed to address this non-fulfillment with the supplier in a manner proportionate to the risk associated with the purchased product.

These temperature sensing probes are used with infant radiant warmers and infant incubators to provide skin or air temperature feedback for maintaining pre-selected temperature settings for neonatal patients in hospital settings.

***DATES OF INSPECTION**
2/26/2026(Thu), 2/27/2026(Fri), 3/03/2026(Tue)

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Annotations to Observations

Observation 1: Promised to correct

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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."