

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax: (718) 662-5661		DATE(S) OF INSPECTION 12/10/2025-12/11/2025 FEI NUMBER 3013337852	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Brian Lynch, CEO			
FIRM NAME Thoracent, LLC		STREET ADDRESS 120 New York Ave, Suite 6W	
CITY, STATE, ZIP CODE, COUNTRY Huntington, NY 11743-2736		TYPE ESTABLISHMENT INSPECTED Complaint File Establishment/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.			
<i>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.</i>			
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Written MDR procedures have not been developed. Specifically, Your firm has not established any written MDR procedures that describe how your firm is required to perform and document the following activities: - Evaluating and investigating complaints that appear to be adverse events. - Reporting adverse events to the FDA as a Medical Device Report (MDR)			
OBSERVATION 2 Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been established. Specifically, Your firm has not established any complaint procedures that specify how your firm is required to receive, review, and maintain complaints.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Preston M Lee, Investigator		DATE ISSUED 12/11/2025 Preston M Lee Investigator Signed By: 2002616804 Date Signed: 12-11-2025 13:12:57

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OBSERVATION 3 Procedures for corrective and preventive action have not been established. Specifically, Your firm does not have procedures for implementing corrective and preventive action.			
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	X Preston M Lee Investigator Signed By: 2002616804 Date Signed: 12-11-2025 13:12:57		
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 2 of 3 PAGES			

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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."