DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	6/22/2026-6/24/2026
	FEI NUMBER 3004063527

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ronald D. Viola, President

FIRM NAME	STREET ADDRESS
First Source, Inc.	3495 Winton Pl Bldg E Ste 1
CITY, STATE, ZIP CODE, COUNTRY Rochester, NY 14623-2824	TYPE ESTABLISHMENT INSPECTED Medical Device 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

Procedures to control design and development changes were not adequately documented.

Specifically, design changes for the iQ Flex M Mobile X-Ray Unit including a design change to the dimensions of the (b) (4) to decrease the chances of damage to the cable and a design change to the (b) (4) to help prevent backing out did not include documentation of design verification or validation and did not include justification for not performing a design validation as required by Design Procedure, SOP-4001 and Product Change Process, SOP-4002, Revision A.

OBSERVATION 2

Corrective action procedures defining the requirements for evaluating the need for action to ensure that nonconformities do not recur and reviewing the effectiveness of corrective action taken have not been adequately documented.

Specifically, 1 of 7 CAPAs reviewed did not include an adequate effectiveness check as required by Corrective and Preventive Action, SOP-9001. Additionally, 3 CAPAs launched in response to observations from the previous FDA inspection identify the root cause as an oversight by the firm, however only corrections for the identified issues were completed and no corrective actions were taken

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Matthew D Schnittker, Investigator	X Matthew D Schnittker Investigator Signed By: Matthew D. Schnittker -S Date Signed: 06-24-2026 13:46:01	6/24/2026

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to prevent the recurrence of the issue.

OBSERVATION 3

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

Specifically, risk assessment procedures documented in Risk Management Procedure, SOP-1002, Revision D requires a determination of severity level and probability of occurrence for risks on a scale of (b) (4) but does not provide clear definitions for each score. The score for probability of occurrence and severity are then combined to determine the risk category, however no instructions are provided for required risk mitigation activities for each risk category. Additionally, the risk assessment completed for the cart portion of the iQ Flex M Mobile X-Ray Unit does not clearly document the harms to patients or end users associated with all identified potential failure modes.

AMENDMENT 1

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Annotations to Observations

Observation 1: Annotation Intentionally Left Blank

Observation 2: Annotation Intentionally Left Blank

Observation 3: Annotation Intentionally Left Blank

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	Matthew D Schnittker, Investigator X Matthew D Schnittker Investigator Signed By: Matthew D. Schnittker -S Date Signed: 06-24-2026 13:46:01	6/24/2026

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."