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	2/11/2026-2/18/2026*
	FEI NUMBER 1000634785

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Peter P. Leonidas , President & CEO

FIRM NAME	STREET ADDRESS
Soma Technology Inc	166 Highland Park Dr
CITY, STATE, ZIP CODE, COUNTRY Bloomfield, CT 06002-5306	TYPE ESTABLISHMENT INSPECTED Initial Importer

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

Written MDR procedures have not been developed and implemented.

Specifically, your firm, Soma Technology Inc., an importer of medical devices, failed to establish written Medical Device Reporting (MDR) procedures as required by federal regulation. No SOP addressing MDR requirements was provided during inspection on 2/12/2026. The Quality Manual (Q-002A, Section 1.0) states: (b) (4)

(b) (4) demonstrating misunderstanding of importer MDR obligations under applicable regulations. Additionally, the complaint handling procedure (SOP S 8.2-1C) lacks MDR evaluation criteria, reporting timelines (b) (4) deaths, (b) (4) serious injuries/malfunctions), and event file requirements as specified in federal regulations. No MDR event files exist, personnel are untrained on MDR requirements, and the firm is not registered for FDA eSubmitter.

***DATES OF INSPECTION**

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: 02-18-2026 11:41:12	2/18/2026

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	2/11/2026-2/18/2026*
	FEI NUMBER 1000634785

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Peter P. Leonidas , President & CEO

FIRM NAME	STREET ADDRESS
Soma Technology Inc	166 Highland Park Dr
CITY, STATE, ZIP CODE, COUNTRY Bloomfield, CT 06002-5306	TYPE ESTABLISHMENT INSPECTED Initial Importer

2/11/2026(Wed), 2/12/2026(Thu), 2/18/2026(Wed)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Eric C Schmitt, Investigator

X Eric C Schmitt
Investigator
Signed By: ERIC C. SCHMITT -S
Date Signed: 02-18-2026
11:41:12

DATE ISSUED
2/18/2026

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	2/11/2026-2/18/2026*
	FEI NUMBER 1000634785

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Peter P. Leonidas , President & CEO

FIRM NAME	STREET ADDRESS
Soma Technology Inc	166 Highland Park Dr
CITY, STATE, ZIP CODE, COUNTRY Bloomfield, CT 06002-5306	TYPE ESTABLISHMENT INSPECTED Initial Importer

Annotations to Observations

Observation 1: Not annotated

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Eric C Schmitt, Investigator X Eric C Schmitt Inves igator Signed By: ERIC C. SCHMITT -S Date Signed: 02-18-2026 11:41:12	2/18/2026

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."