DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	5/13/2024-5/15/2024 FEI NUMBER 3020982310

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Scott Phillips, President

FIRM NAME	STREET ADDRESS
Levo Medical Corporation	455 Boleskine Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Victoria, V8Z 1E7	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 for management review have not been adequately established.

Specifically, the firm's procedures do not adequately define which management members are required for the annual management review.

OBSERVATION 2

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, the firm's procedures do not adequately define the following terminology or their usage, which are essential to ensure effective identification and evaluation of events that may be subject to medical device reporting requirements:

- Regulatory definition for "caused or contributed."
- Regulatory definition for "Become aware".
- Regulatory definition for "information"
- Regulatory usage of "likely to" regarding malfunction and adverse events

Also, the adverse event reportability evaluations were not adequately documented in the complaint files that were reviewed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	John A Sciacchitano, Investigator - Dedicated Device Cadre X John A Sciacchitano Investigator - Dedicated Device Cadre Signed By: John Sciacchitano -S Date Signed: 05-15-2024 16:07:09	5/15/2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	5/13/2024-5/15/2024
	FEI NUMBER 3020982310

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Scott Phillips, President	
FIRM NAME Levo Medical Corporation	STREET ADDRESS 455 Boleskine Rd
CITY, STATE, ZIP CODE, COUNTRY Victoria, V8Z 1E7	TYPE ESTABLISHMENT INSPECTED Manufacturer

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE John A Sciacchitano, Investigator - Dedicated Device Cadre	X John A Sciacchitano Investigator - Dedicated Device Cadre Signed By: John Sciacchitano -S Date Signed: 05-15-2024 16:07:09	DATE ISSUED 5/15/2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	5/13/2024-5/15/2024
	FEI NUMBER 3020982310

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Scott Phillips, President	
FIRM NAME Levo Medical Corporation	STREET ADDRESS 455 Boleskine Rd
CITY, STATE, ZIP CODE, COUNTRY Victoria, V8Z 1E7	TYPE ESTABLISHMENT INSPECTED Manufacturer

Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	John A Sciacchitano, Investigator - Dedicated Device Cadre X John A Sciacchitano Investigator - Dedicated Device Cadre Signed By: John Sciacchitano -S Date Signed: 05-15-2024 16:07:09	5/15/2024

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."