**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 10903 New Hampshire Avenue<br>Silver Spring, MD 20993<br>(301)594-4695 Fax:(301)594-4715 | 1/6/2026-1/9/2026<br>FEI NUMBER<br>3003800159 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sapinder Braich, Corporate Controller

| FIRM NAME | STREET ADDRESS |
|---|---|
| Cadex Electronics Inc. | 22000 Fraserwood Way |
| CITY, STATE, ZIP CODE, COUNTRY<br>Richmond, V6W 1J6 | TYPE ESTABLISHMENT INSPECTED<br>Medical Device Contract 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 receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, the firm's complaints are entered into their complaint handling system for processing (receiving, reviewing, and/or investigating). For example:

| Email Date | Complaint Description |
|---|---|
| 6/17/24 | According to the reporter, during a procedure, the device was assembled according to the factory instructions and it did not work, red light was on. The generator and battery was replaced and it still did not work, the Doctor performed the surgery without the device. |
| 3/14/25 | According to the reporter, during procedure, the red light signal was displayed twice and there was a sound signal after an hour of use. The generator was disconnected and the batteries were replaced, but when the jaw blades were cleaned, they came loose in the doctor's hand. The surgeon decided to change the technology, using a Ligasure to complete the procedure. |
| 3/19/25 | According to the reporter, pre-operatively, the charger did not show the light-emitting diodes (LED) screen even when the charger was plugged in and the motor was working. The charger did not charge the handle. |

**SEE REVERSE OF THIS PAGE**

EMPLOYEE(S) SIGNATURE
Thai T Duong, Investigator

X Thai T Duong
Investigator
Signed By: 1300092605
Date Signed: 01-09-2026
16:42:20

DATE ISSUED
1/9/2026

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 10903 New Hampshire Avenue<br>Silver Spring, MD 20993<br>(301)594-4695 Fax:(301)594-4715 | 1/6/2026-1/9/2026<br>FEI NUMBER<br>3003800159 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sapinder Braich, Corporate Controller

| FIRM NAME | STREET ADDRESS |
|---|---|
| Cadex Electronics Inc. | 22000 Fraserwood Way |
| CITY, STATE, ZIP CODE, COUNTRY<br>Richmond, V6W 1J6 | TYPE ESTABLISHMENT INSPECTED<br>Medical Device Contract Manufacturer |

| | |
|---|---|
| 5/28/25 | According to the reporter, prior to use, the battery charger would not charge and was showing exclamation mark. It was an out of box failure... |

**OBSERVATION 2**

Process control procedures that describe any process controls necessary to ensure conformance to specifications have not been adequately established.

Specifically, on 1/8-9/26, I observed the firm manufacturing the following Lot of products, on the production floor, without any documentation (on each unit to demonstrate that the unit was manufactured in accordance with the DMR):

-Sonicision Battery Chargers – [redacted]

**OBSERVATION 3**

Procedures for finished device acceptance have not been adequately established.

Specifically, the firm's final inspection of the Sonicision Battery Chargers is inadequate in that:

-Failure to define the use of the following sampling plans –

-MIL-STD-105E with default AQL [redacted] for critical defects
-MIL-STD-105E with AQL [redacted] for minor defects

-Failure to document the number of samples used in the final inspection (Visual, Label, Serial numbers, Lot trace information, Packaging, Test, Inspection guidance, and Special Criteria)

For example: DHRs [redacted] and [redacted]

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Thai T Duong, Investigator | X Thai T Duong Investigator Signed By: 1300092605 Date Signed: 01-09-2026 16:42:20 | 1/9/2026 |

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 10903 New Hampshire Avenue<br>Silver Spring, MD 20993<br>(301)594-4695 Fax:(301)594-4715 | 1/6/2026-1/9/2026<br>FEI NUMBER<br>3003800159 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Sapinder Braich, Corporate Controller | |
| FIRM NAME<br>Cadex Electronics Inc. | STREET ADDRESS<br>22000 Fraserwood Way |
| CITY, STATE, ZIP CODE, COUNTRY<br>Richmond, V6W 1J6 | TYPE ESTABLISHMENT INSPECTED<br>Medical Device Contract Manufacturer |

**OBSERVATION 4**

Procedures to control labeling activities have not been established.

Specifically, the firm has yet to establish procedures to control labeling activities for the Sonicision Battery Charger to include: label integrity; labeling inspection; labeling storage; and labeling operations.

In addition, the firm's DHRs from 2025 (pertaining to the Sonicision Battery Chargers) were selected for review during the inspection. Not all labels and labeling used (primary label/UDI Label) for each production unit are documented in the DHR.

For example: DHRs for [redacted] and [redacted]

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Thai T Duong, Investigator<br>X Thai T Duong<br>Investigator<br>Signed By: 1300092605<br>Date Signed: 01-09-2026<br>16:42:20 | 1/9/2026 |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 10903 New Hampshire Avenue<br>Silver Spring, MD 20993<br>(301)594-4695 Fax:(301)594-4715 | 1/6/2026-1/9/2026<br>FEI NUMBER<br>3003800159 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Sapinder Braich, Corporate Controller | |
| FIRM NAME<br>Cadex Electronics Inc. | STREET ADDRESS<br>22000 Fraserwood Way |
| CITY, STATE, ZIP CODE, COUNTRY<br>Richmond, V6W 1J6 | TYPE ESTABLISHMENT INSPECTED<br>Medical Device Contract Manufacturer |

## Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

Observation 4:

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Thai T Duong, Investigator<br>X Thai T Duong Investigator Signed By: 1300092605 Date Signed: 01-09-2026 16:42:20 | 1/9/2026 |

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."