DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	3/16/2026-3/20/2026
	FEI NUMBER 3042586672

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Nicolas J. Mouawad, MD, Clinical Investigator

FIRM NAME	STREET ADDRESS
Nicolas J. Mouawad, MD	1900 Columbus Ave, McLaren Health Care McLaren Bay Region
CITY, STATE, ZIP CODE, COUNTRY Bay City, MI 48708-6831	TYPE ESTABLISHMENT INSPECTED Clinical Investigator

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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:
For Study Protocol Number (b) (4)

OBSERVATION 1

Records of use and disposal of a device that relate to the batch number or code mark of the device are not all accurate and complete.

Device accountability records contain conflicting lot number information that cannot be reconciled.

Specifically, for Subject (b) (6), (b) (7)(C) the Device Accountability Log documents only Lot (b) (4) as deficient (with Lot (b) (4) crossed out); the electronic Case Report Form documents Lot (b) (4) as the deficient lot; source documentation indicates both lots were used; and the Return Goods Authorization was issued for Lot (b) (4)

OBSERVATION 2

Records that relate to the reason why devices were returned to the sponsor are not all complete.

Specifically,

Records of disposition of devices do not adequately document the reason why deficient devices were or were not returned to the sponsor. For example:

- **Subject** (b) (6), (b) (7)(C): Two device deficiencies documented but only one Return Goods Authorization

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Dina A Tallman, Investigator	X Dina A Tallman Investigator Signed By: DINA A. TALLMAN -S Date Signed: 03-20-2026 13:02:16	3/20/2026

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requested (for Lot (b) (4)), with no documentation explaining why the second deficient device (Lot (b) (4)) was not returned to the sponsor.

Subject (b) (6), (b) (7)(C): Device deficiency documented (Lot (b) (4) (b) (4) would not connect to check (b) (4)) but no Return Goods Authorization requested with no documented rationale despite the electronic Case Report Form containing a field to capture this information.

☐ **Subject** (b) (6), (b) (7)(C): Access (b) (4) (Lot (b) (4) was not used due to concerns about product appearance (b) (4) color); however, the reason was not documented in the medical records or source records, not reported in the EDC, nor was the device returned to the sponsor.

OBSERVATION 3

Records of each subject's exposure to the device, including the date and time of each use are not all accurate and complete.

Subject records do not identify subjects on each page of source documentation, preventing verification that records of device exposure correspond to the correct subject.

Specifically, for Subject (b) (6), (b) (7)(C) and Subject (b) (6), (b) (7)(C) the direct access (b) (4) summary assessment source records with the stickers from the device are not labeled with any identifying subject information.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Dina A Tallman, Investigator	X Dina A Tallman Investigator Signed By: DINA A. TALLMAN -S Date Signed: 03-20-2026 13:02:15	3/20/2026

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."