DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	3/16/2026-3/19/2026
	FEI NUMBER 3012309950

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Wilson B. Tarver, VP of Clinical, Regulatory, and Quality

FIRM NAME	STREET ADDRESS
MicroTransponder, Inc.	2802 Flintrock Trce Ste 226
CITY, STATE, ZIP CODE, COUNTRY Lakeway, TX 78738-1769	TYPE ESTABLISHMENT INSPECTED specification developer

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:

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically, your firm has not submitted an MDR report for all reportable events within thirty days of becoming aware of an event. The following complaints describe serious injuries as defined in the medical device regulations and remain in "in progress" status without completed investigations or MDR submissions:

- COMPLAINT-00129, dated 12/17/2025, reports that during an outpatient therapy session that combined external electrical stimulation with (b) (4), the patient lost consciousness and was transported to the emergency department. The person had reported feeling a sensation of electrocution in the thumb.

- COMPLAINT-00134, dated 12/18/2025, reports that a patient experienced a seizure ten minutes into a magnet session. The patient was hospitalized overnight and was given an EEG scan and CT scan prior to discharge the following morning.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Jacey Roy, Investigator

X Jacey Roy
Investigator
Signed By: 2002811114
Date Signed: 03-19-2026
15:45:54

DATE ISSUED
3/19/2026

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Annotations to Observations

Observation 1: Under consideration

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jacey Roy, Investigator X Jacey Roy Investigator Signed By: 2002811114 Date Signed: 03-19-2026 15:45:54	3/19/2026

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."