DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	4/13/2026-4/16/2026
	FEI NUMBER 3008370857

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Troas T. Walling, President

FIRM NAME	STREET ADDRESS
Max Mobility LLC	300 Duke Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lebanon, TN 37090-8115	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.

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 to control design and development changes were not adequately documented.

Specifically,

Your firm failed to adequately evaluate changes that affect safety and function of the SmartDrive Power Assist device originally cleared under K151199 in 2015 intended to "*provide auxiliary power to manual wheelchairs to reduce the pushing power needed by their users…"*. For example:

A. SpeedControl Dial Design Change: Your firm implemented design changes to the SpeedControl dial (rotary controller) that resulted in a Class I recall and subsequent market withdrawal. The risk of the change to introduce the SpeedControl dial was inadequately assessed as evidenced by the field failures causing and/or contributing to serious injuries and necessitating the recall. **According to your firm CAPA 25-035 and CAPA 25-036 have ongoing actions to address this. However, I was unable to verify your firm's corrections during this inspection.**

B. Mobile and Smartwatch Applications: Your firm introduced four (4) new applications (iOS mobile, iOS smartwatch, Android mobile, Android smartwatch) to control the SmartDrive device. These applications represent a significant design change from the original wristband control mechanism. The design change evaluation was inadequate to verify that these software applications did not have an impact on the labeled device specifications.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jamie P Webb, Investigator X Jamie P Webb Investigator Signed By: 2003424907 Date Signed: 04-16-2026 13:34:25	4/16/2026

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CITY, STATE, ZIP CODE, COUNTRY Lebanon, TN 37090-8115	TYPE ESTABLISHMENT INSPECTED Specification Developer

Annotations to Observations

Observation 1: Promised to correct

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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."