DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/17/2026-2/20/2026
	FEI NUMBER 3007883990

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amanda K. Buhrow, Vice President over Operations

FIRM NAME	STREET ADDRESS
Talk To Me Technologies	1100 Technology Pkwy
CITY, STATE, ZIP CODE, COUNTRY Cedar Falls, IA 50613-6955	TYPE ESTABLISHMENT INSPECTED 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 timely complaint handling do not adequately include requirements and responsibilities for receiving and recording information.

Your firm's complaint procedure "QP17 Complaints, Issue 5, 27.01.25" is not adequately established. The procedure fails to include required elements for complaint documentation. Your firm is a manufacturer of (b) (4) product lines of Class II (510(k) Exempt) communication aids—medical devices used to provide auditory responses for children and adults unable to speak. Your firm has identified in the functionality of its risk assessment that a user's inability to communicate is a high risk. Of the six complaints reviewed from your complaint log that are in the date range of January 1, 2022, through April 2, 2025, two (complaints "(b) (6), (b) (7)(C)" and "(b) (6), (b) (7)(C)") involving patients who received a medical device and were unable to communicate using their device lacked the following information: device name and unique device identifier (UDI) or universal product code (UPC).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Clifford F Long, Investigator X Clifford F Long Investigator Signed By: Clifford F. Long -S Date Signed: 02-20-2026 10:10:50	2/20/2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/17/2026-2/20/2026
	FEI NUMBER 3007883990

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Amanda K. Buhrow, Vice President over Operations	
FIRM NAME Talk To Me Technologies	STREET ADDRESS 1100 Technology Pkwy
CITY, STATE, ZIP CODE, COUNTRY Cedar Falls, IA 50613-6955	TYPE ESTABLISHMENT INSPECTED Manufacturer

Annotations to Observations

Observation 1: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Clifford F Long, Investigator		DATE ISSUED 2/20/2026
		X Clifford F Long Investigator Signed By: Clifford F. Long -S Date Signed: 02-20-2026 10:10:50	

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE **INSPECTIONAL OBSERVATIONS** PAGE 2 of 2 PAGES

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."