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 oradevices2firmresponse@fda.hhs.gov	10/20/2021-10/26/2021* FEI NUMBER 3007883990

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Catherine E. Dunning, COO/Co-Owener

FIRM NAME	STREET ADDRESS
Talk To Me Technologies	3508 Terrace Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cedar Falls, IA 50613-6000	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

The device history record does not include, or refer to the location of any unique device identifier (UDI) or universal product code (UPC).

Specifically, your firm failed to have unique device identifier (UDI) labels for medical devices manufactured.

OBSERVATION 2

Document control procedures have not been adequately established.

Specifically, your firm failed to establish document control procedures. Your firms Complaint Handling procedure, CAPA procedure, and Recalls procedure does not contain authorizing signatures and dates to verify that the procedure to the approved and implemented.

OBSERVATION 3

AMENDMENT 1

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: 01-07-2022 09:35:12	1/7/2022

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Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been established.

Specifically, your firm failed to establish procedures for receiving sub-assembly components purchased from venders.

***DATES OF INSPECTION**
10/20/2021(Wed), 10/21/2021(Thu), 10/26/2021(Tue)

AMENDMENT 1

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

AMENDMENT 1

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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."