**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 19701 Fairchild<br>Irvine, CA 92612-2445<br>(949)608-2900 Fax:(949)608-4417 | 2/10/2026-2/13/2026 |
| | FEI NUMBER<br>3003240904 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Timothy L Truitt, President

| FIRM NAME | STREET ADDRESS |
|---|---|
| Truer Medical Inc | 1050 N Batavia St Ste C |
| CITY, STATE, ZIP CODE, COUNTRY<br>Orange, CA 92867-5542 | TYPE ESTABLISHMENT INSPECTED<br>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.

**DURING AN INSPECTION OF YOUR FIRM I OBSERVED:**

## OBSERVATION 1

A design and development file was not maintained for each medical device type or medical device family.

Specifically,

Your firm is a manufacturer of Class II medical devices including continuous measurement thermometers and esophageal stethoscopes. Section 4.13 of your firm's procedure, SOP 4.1, Rev K, Design Control, 3/7/24, defines the design history file (DHF). Section 6.9 of SOP 4.1, Rev K, details your firm's procedure for the creation and maintenance of the design history file. This includes the statement that (b) (4)
(b) (4) Despite these internal requirements, your firm has not established or maintained a design history file, nor a design and development file, for the following commercially distributed Class II devices: the General Purpose Temperature Probe, the Esophageal Stethoscope Tubes, and the Skin Sensor Probes.

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| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Jordan I Abel, Investigator<br>X Jordan I Abel Investigator Signed By: 2004376737 Date Signed: 02-13-2026 11:44:33 | 2/13/2026 |

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| Timothy L Truitt, President | |
| FIRM NAME<br>Truer Medical Inc | STREET ADDRESS<br>1050 N Batavia St Ste C |
| CITY, STATE, ZIP CODE, COUNTRY<br>Orange, CA 92867-5542 | TYPE ESTABLISHMENT INSPECTED<br>Manufacturer |

## Annotations to Observations

Observation 1:

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE<br>Jordan I Abel, Investigator | DATE ISSUED<br>2/13/2026 |
|---|---|---|

X Jordan I Abel
Investigator
Signed By: 2004376737
Date Signed: 02-13-2026
11:44:33

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."