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	3/23/2026-3/26/2026
	FEI NUMBER 3007697249

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert E. Davis, President

FIRM NAME	STREET ADDRESS
Footprint Medical, Inc.	5823 Sebastian Pl
CITY, STATE, ZIP CODE, COUNTRY San Antonio, TX 78249	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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Control over outsourced processes that affect product conformity to requirements do not include written quality agreements.

Specifically, your firm's SOP-10, Purchasing, Version 1.0, effective 05/12/2022, which governs the control over outsourced processes, does not include requirements for written quality agreements to ensure product conformity.

For example, your firm does not have written quality agreements with the following suppliers used in the production of Class II Peripherally Inserted Central Catheters (PICC) intended for neonatal and small pediatric patients:

- Extruded tubing used in the body of the catheter
- Steel rods used in the accessory stylet
- Pouches used to contain and seal sterile product

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Yuliana Hernandez-Magana, Investigator

X Yuliana Hernandez-Magana Investigator Signed By: YULIANA HERNANDEZ-MAGANA -S Date Signed: 03-26-2026 11:44:18

DATE ISSUED
3/26/2026

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Annotations to Observations

Observation 1: Under consideration

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Yuliana Hernandez-Magana, Investigator X Yuliana Hernandez-Magana Investigator Signed By: YULIANA HERNANDEZ-MAGANA -S Date Signed: 03-26-2026 11:44:18	3/26/2026

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."