DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	11/13/2025-12/1/2025*
	FEI NUMBER 3016567400

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Alessandra P. Pluchino, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Focalyx Technologies, LLC.	2140 W 68th St Ste 204
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hialeah, FL 33016-1815	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

Design validation did not ensure the device conforms to defined user needs and intended uses.

Specifically,

Your firm failed to verify and validate that your class II medical device software, (b)(4), used for diagnosis and treatment of prostate diseases including cancer, functions as intended with an upgraded operating system. Your document "Benefit-Risk Analysis and Risk Management Off the Shelf Software," (b)(4), Version 4, dated December 14, 2023, Section 8 (b)(4) Software Control states: "The Design Change Control process shall be followed to bring the (b)(4) device up to date with the latest versions of supporting software as required." Support for the operating system for which (b)(4) was originally designed was discontinued on October 14, 2025. Your firm failed to conduct the necessary verification and validation activities to ensure software compatibility with an operating system upgrade prior to this discontinuation. As of November 14, 2025, approximately (b)(4) medical procedures have been performed using (b)(4) across (b)(4) host computers since January 1, 2025.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Marvin A Marenco, Investigator	X Marvin A Marenco Investigator Signed By: MARVIN A. MARENCO -S Date Signed: 12-01-2025 10:47:04	12/1/2025

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The labels of the medical device(s) do not bear a unique device identifier (UDI) that meet the requirements of 801 Subpart B and 21 CFR 830.

Specifically,

Your firm has not submitted the required medical device information to the Global Unique Device Identification Database (GUDID).

***DATES OF INSPECTION**
11/13/2025(Thu), 11/14/2025(Fri), 11/17/2025(Mon), 11/18/2025(Tue), 11/20/2025(Thu), 11/25/2025(Tue), 12/01/2025(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Marvin A Marenco, Investigator X Marvin A Marenco Investigator Signed By: MARVIN A. MARENCO -S Date Signed: 12-01-2025 10:47:04	12/1/2025

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Annotations to Observations

Observation 1:

Observation 2:

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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."