DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	2/17/2026-2/20/2026
	FEI NUMBER 3033300766

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jonathan J. Woodward, General Manager and Chief Technology Officer

FIRM NAME	STREET ADDRESS
ANALYTICS FOR LIFE INC.	3 Bethesda Metro Ctr Ste 700
CITY, STATE, ZIP CODE, COUNTRY Bethesda, MD 20814-6300	TYPE ESTABLISHMENT INSPECTED Medical Device 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

Complaint handling records were not maintained.

Specifically,

Your CorVista System is designed with a Signal Quality Assessment (SQA) attribute that ensure patient signals acquired during use, meet defined Signal Quality Scores prior to processing with either add-on Coronary Artery Disease (CAD) or Pulmonary Hypertension (PH) disease state algorithms. To avoid incorrect results, a patient signal will not be further processed by the add-on CAD or PH disease state algorithms where there is SQA failure. This will prompt repeating signal acquisition (patient testing) resulting in an outcome of delay in patient care (diagnosis and treatment).

Upon reviewing your Quality Management System records, I observed that you did identify SQA failure rate of (b) (4) in the (b) (4) of 2024. This was reduced to (b) (4) in (b) (4) of 2025. SQA failure is assigned complaint code (b) (4) A further review of your records indicate that between 04/01/2024 and 02/17/2026, you received report of about 980 events of SQA failure. However, you failed to open a complaint record for each event of SQA failure. As such, SQA failure complaints are not evaluated for reportability and processed as stipulated in the regulation and standard.

OBSERVATION 2

Procedures for the feedback process have not been adequately documented to include provisions for gathering data from production and post-production activities.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jude C Dike, Investigator X Jude C Dike Investigator Signed By: 2000620664 Date Signed: 02-20-2026 14:04:43	2/20/2026

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Specifically,

Your Feedback procedure is documented in section 5.2.3 of your Complaint Handling procedure (Doc#: SOP1090, Rev. 5). Upon reviewing the procedure, I observed the following deficiencies,

- There is no defined method for obtaining and using information relating to whether you have met customer requirements.
- There is no provision to gather data from production as well as post-production activities.
- There is no requirement that the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as product realization or improvement processes.

Upon reviewing your Quality Management System records, I identified the following feedback,

1. A possible improvement for the device to help users get real-time or near real-time feedback on PPG positioning on the finger, noting difficulties he has experienced with PPG devices due to their need to be precisely positioned. Discussed during 2024 (b) (4) management review.
2. Degradation of on-time training over time, with group having (b) (4) on time training; may be due to outside contractor groups. Discussed during 2024 (b) (4) management review.
3. Suggestion that a potential fix to SQA failure would be (b) (4) to include an instruction to (b) (4) the PPG signal. Discussed during 2024 (b) (4) management review.
4. Opportunities for improvement documented in section 6.3 of your 2024 Internal Audit Report.
5. Opportunities for improvement documented in section 6.3 of your 2025 Internal Audit Report.

These feedbacks were not processed as stipulated in the standard.

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

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	Jude C Dike, Investigator	X Jude C Dike Investigator Signed By: 2000620664 Date Signed: 02-20-2026 14:04:43	2/20/2026

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."