DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	2/17/2026-2/20/2026
	FEI NUMBER 3027535342

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ashok Roy, President

FIRM NAME	STREET ADDRESS
Seniorlife Technologies Inc	1400 112th Ave Se Ste 100
CITY, STATE, ZIP CODE, COUNTRY Bellevue, WA 98004-6901	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.

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 WE OBSERVED:

OBSERVATION 1

A system to assign unique device identification (UDI) to the medical device was not documented.

Specifically,

Your firm does not adhere to UDI labeling conditions for identified medical devices under the associated requirement. This includes formulating the process for ensuring each medical device bears the UDI within its labeling, and ensuring each UDI is appropriately registered in the UDI database. When asked about UDI labeling affixed to the Mobility Metrics Tracker software application, intended to measure exercise data for general exercise tracking, you were unable to provide evidence for this requirement.

OBSERVATION 2

Design and development procedures were not documented.

Specifically,

Your firm failed to document a procedure to control the design, planning, and development of the device in order to ensure that specified design requirements are met. When asked about the procedure governing the process from design planning to validation and changes, you were unable to provide evidence for its establishment.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brian R Hendricks, Investigator Kevin T Le, Inspector X Brian R Hendricks Investigator Signed By: Brian R. Hendricks Jr - S Date Signed: 02-20-2026 09:50:48	2/20/2026

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OBSERVATION 3

Procedures for validation of processes did not adequately include requirements for records and use of specific methods, procedures, and acceptance criteria.

Specifically,

Your firm's procedure SOP-QMS-005, "Software Change Control," states that changes developed in a secure repository must be signed, code review and unit tests must hit (b) (4) coverage, (b) (4) testing is conducted on (b) (4) devices, and a release checklist must be signed for each software iteration. The procedure fails to identify the signing authority for the secure repository and designated location for the record, in addition to designated locations for code review, (b) (4) testing, and signed release checklists. The procedure also fails to reference the Business Associate Agreement for Protected Health Information, as noted in your firm's Quality Agreement Summary. You were unable to provide the requested records as noted in the procedure and when asked about the control of records, you were unable to provide adequate information in this regard.

OBSERVATION 4

Outsourced processes that affect product conformity to requirements were not monitored and controlled.

Specifically,

Your firm's Quality Agreement Summary states that an (b) (4) review is conducted for compliance certifications to verify ongoing suitability related to cloud services from Company A. This includes the process to ensure cloud hosting compliance for the Mobility Metrics Tracker production environment. When asked about the documentation for your referenced (b) (4) review, you were unable to provide evidence for its establishment.

OBSERVATION 5

Internal audits have not been adequately conducted at planned intervals to determine whether the QMS is effectively implemented and maintained.

Specifically,

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Your firm does not adhere to the requirement that each organization shall document procedures for quality audits and conduct such audits to assure that the quality system is in compliance. Your firm's procedure SOP-QMS-003, "Internal Audit Program," states that management representatives mandate a (b) (4) system audit at least (b) (4) per calendar year. Internal Audit Report No. 1, dated 07/12/2025, contained two objectives related to design controls. Internal Audit Report No. 2, dated 11/15/2025, contained two objectives related to design controls. You stated there were no other quality audits conducted for your firm. When asked about the absence of objectives related to other areas of the quality system as referenced in the procedure, you were unable to provide justification in this regard.

OBSERVATION 6

Quality management system processes were not adequately managed.

Specifically,

Your firm does not adhere to the requirement that each organization shall document, monitor, and maintain effectiveness of a quality system. This includes formulating the process for ensuring the availability of resources are controlled and required administrative arrangements, to include defined criteria for operations, are managed to ensure overall effectiveness. When asked about the lack of procedures and resources within your firm's quality system for necessary alignment to regulatory standards, you were unable to provide justification in this regard.

OBSERVATION 7

Documents required by the quality management system have not been controlled.

Specifically,

Your firm does not adhere to the requirement that each organization shall ensure documents are reviewed and approved. This includes formulating the process for ensuring the adequacy of documents prior to issue. Your firm's procedure SOP-QMS-006, "Document Control," states that every SOP and manual must include a unique ID, version number, and revision history table. The procedure also states that all QMS documents must be reviewed for adequacy and approved by the management representatives before issuance. Your firm released and implemented (b) (4) procedures that do not contain, and are not associated with, information that includes approval,

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dates, revisions, or signatures of the official who reviewed the documents. These procedures include your firm's Corrective and Preventive Action (CAPA) procedure, Complaint and MDR Handling procedure, Internal Audit Program procedure, Training and Competence procedure, Software Change Control procedure, Document Control procedure, Risk Management procedure, and Recalls procedure. When asked about the lack of document control, you were unable to provide justification in this regard.

X Kevin T Le
Inspector
Signed By: 2003985283
Date Signed: 02-20-2026 09:51:22

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EMPLOYEE(S) SIGNATURE

Brian R Hendricks, Investigator
Kevin T Le, Inspector

X Brian R Hendricks
Investigator
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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

Observation 6: Promised to correct

Observation 7: Promised to correct

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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."