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	3/16/2026-3/20/2026
	FEI NUMBER 3036039911

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Steven R. Daly, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Inmedix, Inc.	19658 Marine View Dr Sw
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Normandy Park, WA 98166-4118	Specification Developer

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 and development validation was not adequately performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use.

Specifically,

Your firm failed to adequately document software validation for the Class II CloudHRV System, which is intended to acquire, display, and record electrocardiographic information to measure heart rate variability. Page (b) (4) section (b) (4) of your firm's Design and Development procedure, (b) (4) states that (b) (4) (b) (4) Page (b) (4) of your firm's Design Review, (b) (4) specifies the software validation report as a deliverable for the design and development plan. However, page (b) (4) references the software verification report no. (b) (4) as software validation. A review of the validation report no. (b) (4) revealed that software verification was used as evidence of validation results. The validation documentation provided did not include evidence of comprehensive software validation to include integration testing, code coverage analysis, or validation of data integrity for network and cloud services. When asked about the absence of documentation for software validation, your firm's manager for regulatory and quality assurance was unable to provide justification in this regard.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Brian R Hendricks, Investigator	X Brian R Hendricks Investigator Signed By: Brian R. Hendricks Jr - S Date Signed: 03-20-2026 11:03:41	3/20/2026

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Procedures for timely complaint handling have not been adequately documented.

Specifically,

Your firm does not adhere to the requirement that each organization shall process complaints in a timely manner for nine out of eleven complaints reviewed. Page (b) (4) of your firm's Complaint Handling procedure, Doc No. SOP-12, states that "complaints shall be processed in a uniform and timely manner" and "Complaint Management Personnel will maintain and ensure all complaint records are completed and closed out within (b) (4) business days of receipt, unless extended with documented justification."

For example:

a) Complaint case no. CF-6 related to the CloudHRV System opened on 07/28/2025 and remained open during the time of this inspection. The complaint references an entry error of patient data merged files.

b) Complaint case no. CF-7 related to the CloudHRV System opened on 08/07/2025 and remained open during the time of this inspection. The complaint references an Analytics Cloud upload failure.

c) Complaint case no. CF-8 related to the CloudHRV System opened on 08/21/2025 and remained open during the time of this inspection. The complaint references a network authentication error.

d) Complaint case no. CF-10 related to the CloudHRV System opened on 09/25/2025 and remained open during the time of this inspection. The complaint references a network request failure.

e) Complaint case no. CF-12 related to the CloudHRV System opened on 09/24/2025 and remained open during the time of this inspection. The complaint references an ECG measurement issue.

f) Complaint case no. CF-13 related to the CloudHRV System opened on 10/23/2025 and remained open during the time of this inspection. The complaint references a network authentication error.

g) Complaint case no. CF-14 related to the CloudHRV System opened on 10/27/2025 and remained open during the time of this inspection. The complaint references a tablet charging issue.

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h) Complaint case no. CF-15 related to the CloudHRV System opened on 12/08/2025 and remained open during the time of this inspection. The complaint references a network authorization error.

i) Complaint case no. CF-17 related to the CloudHRV System opened on 09/18/2025 and remained open during the time of this inspection. The complaint references an invalid assessment error.

Your manager for regulatory and quality assurance was unable to provide adequate justification for the established complaint time lines and procedural institution of observed complaint processing activities.

OBSERVATION 3

Procedures for management review have not been adequately documented.

Specifically,

Your firm does not adhere to the requirement that each organization shall document reviews of the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. Page (b)(4) of your firm's Management Responsibility and Review procedure, Doc No. SOP-02, states that "the Management Representative will coordinate and chair a periodic meeting at planned intervals adequate to monitor and address QMS performance and regulatory requirements" and "Management Review shall be conducted at a minimum (b) (4) Your manager for regulatory and quality assurance stated there have been no management review meetings conducted for your firm. When asked about the absence of management review meetings, your firm's manager for regulatory and quality assurance was unable to provide adequate justification in this regard.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: 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."