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	4/8/2026-4/14/2026* FEI NUMBER 3022527636

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Arna I. Stoll, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Wavely Diagnostics, Inc.	2319 N 45th St Ste 107
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Seattle, WA 98103-6947	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 Wavely Middle Ear Fluid Scanner device, which is intended to detect the presence of middle ear fluid in children over 6 months old. (b) (4)

(b) (4)

(b) (4) A review of design documentation revealed there was no report of software validation to include documented evidence of penetration testing, secure coding review, validation of data integrity, and a summary of tests performed. When asked to provide (b) (4) (b) (4) your firm did not have the requested document. When asked about the absence of documentation for software validation, your firm's Product and Human Factors consultant 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: 04-14-2026 09:59:14	4/14/2026

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

Specifically,

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-1027, "Internal Audit," states that the audit schedule reflects an audit of each element of the system at least (b) (4) A review of records revealed that one quality audit was conducted on 11/16/2022 and there were no other quality audits conducted for your firm. When asked about the lack of internal audits in accordance with the procedure and regulations, your firm's Chief Executive Officer was unable to provide justification in this regard.

OBSERVATION 3

The monitoring of suppliers was not adequately planned.

Specifically,

Your firm did not comply with your SOP for supplier selection and monitoring. Page 6, section 7.5 of the Supplier Quality Management procedure, Doc No. SOP-1033, states that "audits are performed to evaluate (b) (4) suppliers and (b) (4) The procedure identifies required audits for critical level (b) (4) suppliers, and Company A is listed on your approved supplier list as a critical level (b) (4) upplier as of 10/12/2021. A review of records revealed that no supplier audits were conducted for Company A. A further review of the approved supplier list revealed no information entered or generated for the supplier audit and review plan section. When asked why the supplier audits were not initiated, your firm's Chief Executive Officer was unable to provide justification in this regard.

OBSERVATION 4

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

Specifically,

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Your firm's Supplier Quality Management procedure, Doc No. SOP-1033, states that a Quality Agreement is required for level (b) (4) and level (b) (4) suppliers. Company B is listed on your Approved Supplier List as a critical level (b) (4) supplier with no Quality Agreement required. Company B is an outsourced vendor that provides the paper ear tip component of your medical device, which is a part of design specifications and a design requirement that affects product conformity. When asked about the lack of a written Quality Agreement for the supplier and the determination of directives within the procedure, your firm's Chief Executive Officer did not have adequate information or evidence for the understanding of this requirement.

***DATES OF INSPECTION**

4/08/2026(Wed), 4/09/2026(Thu), 4/10/2026(Fri), 4/13/2026(Mon), 4/14/2026(Tue)

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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

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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."