DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	7/21/2026-7/24/2026* FEI NUMBER 3003694926

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amy L. Rolen , Operation Manager

FIRM NAME	STREET ADDRESS
AdDent, Inc.	43 Miry Brook Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Danbury, CT 06810-7407	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

A record for each medical device or batch of medical devices that provides specified traceability and identifies the amount manufactured and amount approved for distribution has not been established and maintained and verified and approved.

Specifically,

Your firm failed to establish and maintain complete batch records for the (b) (4), a class II medical device. Section 4.3.6 of your procedure "Operations Control" PRM 06, Rev. B, dated 4/4/18, states that Device History Files must be reviewed and signed off by production and Quality assurance for each batch of product ready for delivery. DHR checklist (FR08) is prepared by production including complete traceability information and references to testing and inspection reports and reviewed and approved by QA before lot of products to be released as ready for delivery. However,

a) Your firm has manufactured a total of (b) (4) (b) (4) medical devices from January 2024-June 2026, (Serial# (b) (4)) according to final test sheets. However, only (b) (4) serial numbers (serial # (b) (4), and serial # (b) (4)) have a documented

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EMPLOYEE(S) SIGNATURE
Katarzyna Plona, Investigator

X Katarzyna Plona Investigator Signed By: KATARZYNA PLONA -S Date Signed: 07-24-2026 10:32:54

DATE ISSUED
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verification and approval for distribution on the Finished Product Release forms (FR08). There are no documented Finished Product Release (FR08) for the remaining (b) (4) devices.

b) (b) (4) devices serial numbers (b) (4) were distributed without meeting the minimum acceptance criteria for visible light which is (b) (4) The recorded output for these devices is 1018, 1085, 1378, 1386, 766,849, 895,273 respectively.

c) Traceability for the (b) (4) device is incomplete, as lot numbers of components used to manufacture each batch of devices is not documented. Your firm's operation manager stated that only the main PCB lot number is documented. (b) (4) for the batches of devices manufactured.

OBSERVATION 2

The significance of the design and development change to regulatory requirements for the medical device and its intended use was not adequately determined.

Specifically,

Your firm's procedure "Design & Development" PRM 13, Rev. B dated 4/4/18, section 4.3.2 states "legal and statutory requirements for the appropriate country market or country must be identified". However, the procedure does not define the requirements of an assessment to determine if a new marketing submission for clearance or approval is required. Your firm redesigned the (b) (4) device cleared under (b) (4), and released a new device in 2024 the

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"(b) (4)" which was not adequately evaluated to determine if the device requires a new marketing submission prior to distribution.

OBSERVATION 3

Criteria for the evaluation and selection of suppliers were not proportionate to the risk associated with the medical device.

Specifically,

Your firm's procedure "Purchasing" PRM 07, Rev. C, dated 6/20/23, section 4.1.5 states "The list of approved suppliers will be included on the Preferred Supplier Register (FR10)". Section 4.1.7 states the list of approved suppliers must be reviewed at least (b) (4) and that inclusion on the list will be based on supplier performance". Your firm has not maintained or updated the preferred supplier register since 2016. Per your operations manager only critical suppliers are evaluated on (b) (4) basis and only if there was a purchase order within the monitoring period; all other suppliers are not evaluated. However, your firm has not defined which suppliers are critical nor the extent of control of those suppliers in your procedures.

OBSERVATION 4

Records of the verification of purchased product were not adequately maintained.

Specifically,

Your firm's procedure "Purchasing" PRM 07, Rev. C, dated 6/20/23, section 4.3.1 states "All

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products must be verified /recorded against information and any special testing requirements shown on the purchase order and SOPs defined by engineering. This shall verify that the purchased product fulfils specified requirements, are completed, have proper identity and are undamaged." However, for components received that do not require an inspection there is no documented verification that the purchased product meets the requirements of the PO. There is no documentation of receiving activities, such as signature of the person accepting the goods, the date of receipt, nor if the quantity order is corrected, if product is undamaged etc.

OBSERVATION 5

The document control procedure does not adequately define controls needed to review and approve documents for adequacy before use and ensure that current versions of applicable documents are available at point of use.

Specifically,

Your firm's document control is inadequate:

a) The released procedure "Medical Device Reporting" PRM 15 states Revision C effective 4/4/18. However, there is no Document Change Control (DCN) for the release of version B or C of the procedure. Per the DCN log only version A was released on 4/26/15. Your firm's Document Master List and Register also states PRM 15 rev. C effective 4/4/18.

b) Your released "Recall & Advisory Notices" PRM 16, states Revision B effective 1/30/23. However, per DCN number 109 the procedure was revised to version B effective 12/5/13, and per DCN 111, version C was released 4/25/16. Your firm's Document Master List and Register also states PRM 16 Revision B effective 1/30/23.

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c) The Bill of Material (BOM) for the (b) (4) device has not been updated to reflect current version of components. The BOM lists the (b) (4) charger PC board assembly as revision (b) (4) however, the purchased component is currently on revision (b) (4)

***DATES OF INSPECTION**
7/21/2026(Tue), 7/22/2026(Wed), 7/24/2026(Fri)

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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

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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."