DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	11/3/2025-11/5/2025
	FEI NUMBER 1000113887

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Alfred (NMI) Perez Jr, Executive Vice President

FIRM NAME	STREET ADDRESS
Medidenta	3575 W Post Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Las Vegas, NV 89118-3867	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

Procedures or instructions for performing servicing activities and verifying that servicing meets specified requirements have not been adequately established.

Specifically,

a) Failure to Follow Written Service Report Procedures

Your firm failed to follow its own written procedure for service reports as outlined in "**CORPORATE GOOD MANUFACTURING PRACTICES cGMP,**" section 820.200 Servicing procedures (page 38). Service reports shall be documented and shall include the following information in Form FM1000136:

1. "(1) The name of the device serviced; Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;"

2. "(6) The test and inspection data."

b) Failure to Maintain Adequate Service Records

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Clifford F Long, Investigator	X Clifford F Long Investigator Signed By: Clifford F. Long -S Date Signed: 11-05-2025 16:47:03	11/5/2025

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Your firm failed to maintain adequate service records as required. Your firm completed (b) (4) services from January 1, 2024, to November 4, 2025, on the AW25C and AW30C Autoscaler, a Class II medical device designed for dental prophylaxis treatment and used for scaling and cleaning tooth surfaces in conjunction with other prophylactic measures. One hundred percent (100%) of the reviewed service reports (22 out of 22) from January 2024 to November 4, 2025, were missing the unique device identifier (UDI) and the test and inspection data requirements.

OBSERVATION 2

Procedures for device history records have not been adequately established.

Specifically, your firm failed to follow its own written procedure for service reports as outlined in "CORPORATE GOOD MANUFACTURING PRACTICES cGMP," section 820.184 Device History Record (page 37). The Device History Record (DHR) shall include, or refer to the location of, the following information:

1.(d) The acceptance records which demonstrate the device is manufactured in accordance with the Device Master Record (DMR).

From January 1, 2023, to November 4, 2025, the firm manufactured and sold (b) (4) units of the AW25C and AW30C Autoscaler, a Class II medical device designed for dental prophylaxis treatment and used for scaling and cleaning tooth surfaces in conjunction with other prophylactic measures.

One hundred percent (100%) of the reviewed device history records (6 of 6) for the AW25C and AW30C Autoscaler do not demonstrate that the devices were produced in accordance with the device master record or that they met specifications prior to release.

The device history records do not include the testing performed, testing criteria, testing results, or the equipment used to perform the testing procedures. The Device History Records (DHR) for the

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Ultrasonic Dental Tooth Scaler fail to show compliance with manufacturing requirements and specification adherence before distribution.

This issue was also noted in the firm's Remote Regulatory Assessment conducted from February 23, 2022, to March 4, 2022, in the Findings and Corrections section.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: 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."