DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	3/10/2026-3/12/2026
	FEI NUMBER 3000719964

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Johnny (nmi) Nguyen, Plant Manager

FIRM NAME	STREET ADDRESS
Pac-dent, Inc.	670 Endeavor Cir
CITY, STATE, ZIP CODE, COUNTRY Brea, CA 92821-2949	TYPE ESTABLISHMENT INSPECTED Specification Developer/Repackager/Relabeler

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

The correct unique device identifier (UDI) information regarding device identifier portion of the UDI assigned to the version or model, proprietary, trade, or brand name of the device as it appears on the label, version or model or similar reference that appears on the label of the device and the type of production identifiers that appears on the label of the device was not provided to the FDA via the Global Unique Device Identification Database (GUDID).

Specifically,

Review of your firm's Class II devices UDIs are not present in the GUDID database:

- Rodin™ Sculpture 2.0 (00815967028215)
- Rodin™ Denture Base 2.0 (00815967029342)

Both devices are labeled with unique device identifiers and have been commercially distributed, but the required device identification and device attributes have not been submitted to GUDID.

Additionally, your firm has not established any written procedures for assigning, maintaining, or

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Marlo-Ian M Alintanahin, Investigator	X Marlo-Ian M Alintanahin Investigator Signed By: Marlo Ian M. Alintanahin -S Date Signed: 03-12-2026 10:12:09	3/12/2026

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managing unique device identifiers.

OBSERVATION 2

Records of the results of re-evaluation of supplier capability or performance were not maintained.

Specifically,

Your firm did not reevaluate Supplier A, a critical supplier of finished Class II devices, and your firm has no provisions for supplier reevaluation of critical suppliers. Your firm's supplier evaluation procedure, SOP QA30, Rev. 2, Effective Date: 11/1/24, does not address reevaluation of approved critical suppliers.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Marlo-Ian M Alintanahin, Investigator	X Marlo-Ian M Alintanahin Investigator Signed By: Marlo Ian M. Alintanahin -S Date Signed: 03-12-2026 10:12:09	DATE ISSUED 3/12/2026

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."