DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	2/10/2026-2/11/2026
	FEI NUMBER 3036042026

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Omar (nmi) Kasani, Manager

FIRM NAME	STREET ADDRESS
Tiadent Inc	1627 Cortex Midtown Pl Ste 110, 2234 1ST STREET
CITY, STATE, ZIP CODE, COUNTRY Rosenberg, TX 77471	TYPE ESTABLISHMENT INSPECTED Manufacurer (Initial Importer)

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 risk-based approach to the control of the appropriate processes needed for the quality management system has not been applied.

Specifically,

TiaDent Inc failed to apply a risk-based approach during product realization, to the following Class II medical devices, subject to the application of risk management:

(a) Portable Air Compressor (Product code: BTI), with the intended use to be used during general surgery, anesthesiology.

(b) IntraOral Camera (Product code: QJK) with the intended use for dental/endodontic procedures to capture a digital image, using a light source and camera, intraoral or extraoral, the topographical characteristics of teeth or a stone model. It is a software based optical impression system for CAD/CAM.

(c) (b) (4) (Product code: KKO) , with the intended use by infants, for medical purposes, to soothe gums during the teething process.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jocelyn C Turner, Investigator - Dedicated Device Cadre X Jocelyn C Turner Investigator - Dedicated Device Cadre Signed By: JOCELYN C. TURNER Date Signed: 02-11-2026 14:11:26	2/11/2026

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According to your documented Risk Analysis Report (TD-TX-003, edition: A/0, November 20, 2024), a formal risk assessment was never performed for the above listed Class II medical devices to identify hazards, identify failure modes, decide who might be harmed and how; evaluate the risks (severity & occurrence), identify the level of this risk, identify a control measures to take in the event of its occurrence, recalculate the risk (review your assessment) and reduce this residual risk to the patient, to an acceptable level,.

Your Quality Manual (TD-QM-01, Edition: A/0, 2024/11/11 - Section 0.1 (p. 3) documents that your firm is ISO 13485:2016 compliant.

OBSERVATION 2
Written MDR procedures have not been developed, maintained and implemented.

Specifically,

TiaDent Inc is a Manufacturer (Initial Importer) of 22- Class I and 03-Class II medical devices: (a) Intraoral Camera; (b) (b) (4) and (c) Portable Air Compressor; imported from (b) (4) & intended for the U. S. market.

TiaDent does not have Medical Device Reporting (MDR) procedures with a system for collecting & analyzing information from adverse events and malfunctions, reported as complaints, involving medical devices, to the FDA.

Your firm's Complaint Handling procedure, located in the Quality Manual (TD-QM-01, Edition: A/0, 2024/11/11), Section 8.2.2, fails to address how your firm will determine whether the complaint represents an adverse event, which is required to be reported to the U. S. Food & Drug Administration (FDA) under 21 CFR Part 803 - Medical Device Reporting (MDR).

OBSERVATION 3
The labels of the medical device(s) do not bear a unique device identifier (UDI) that meet the requirements of 801 Subpart B and 21 CFR 830.

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Specifically,

TiaDent Inc is registered and listed with the U. S. Food & Drug Administration as a Manufacturer (Initial Importer) of 22-Class I dental/endodontic and general surgery medical devices and 03-Class II medical devices: (a)(b) (4) (b)(b) (4) and (c)(b) (4) ; imported from (b) (4) & intended for the USA market.

Your firm has not registered with GUDID, nor provided a device identifier to the Global Unique Device Identification Database (GUDID) in accordance with the UDI requirement, for these 25 medical devices (22 – Class I and 3 – Class 2), if required.

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Annotations to Observations

Observation 1: Under consideration

Observation 2: Under consideration

Observation 3: Under consideration

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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."