DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	3/31/2026-4/6/2026* FEI NUMBER 3006650414

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Bradley J. Chott, Quality and Regulatory Compliance Manager

FIRM NAME	STREET ADDRESS
National Dentex LLC, dba NDX Keller	160 Larkin Williams Ind Ct
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fenton, MO 63026-2409	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 risk-based approach to the control of the appropriate processes needed for the quality management system has not been applied.

When requested on March 31, 2026, National Dentex LLC could not provide:

1. Risk assessment documentation identifying risks to product quality and regulatory compliance associated with Quality Management System (QMS) processes
2. Documentation of risk controls implemented for identified process risks, including residual risk levels after control implementation
3. Evidence of periodic review and updating of process risk assessments

For example, the firm's quality manual does not describe a risk-based approach to QMS processes, and when asked to provide risk assessment documentation for specific processes such as complaint handling and product realization, the firm could not demonstrate how risks to product quality or regulatory compliance were identified, evaluated, or controlled.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Edward E Lockwood, Investigator X Edward E Lockwood Investigator Signed By: EDWARD E. LOCKWOOD -S Date Signed: 04-06-2026 11:30:48	4/6/2026

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OBSERVATION 2

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.

Specifically, National Dentex is distributing the NTI-tss Plus (510(k) K010876, Product Code OCO) without a Unique Device Identifier (UDI) on the device labeling, as required by 21 CFR 801.20.

During the inspection on 3/31/2026, I observed that an NTI-tss Plus device and packaging lacked UDI labeling.

Your firm distributes approximately (b) (4) units of this device (b) (4)

OBSERVATION 3

A design and development file was not maintained for each medical device type or medical device family.

Specifically, National Dentex is the specification developer, manufacturer, and distributor of the ClearDream (510(k) K133390, cleared October 16, 2014, an FDA Class II medical device, product code LRK).

During the inspection on April 2, 2026, I requested the design and development file for the ClearDream device. You stated that the 510(k) submittal was handled by a consultant, you could not locate the design and development file(s) on site, and the consultant may have the design and development documentation.

The firm was unable to provide the Design and Development file for review.

***DATES OF INSPECTION**

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3/31/2026(Tue), 4/01/2026(Wed), 4/02/2026(Thu), 4/06/2026(Mon)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: 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."