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	11/10/2025-11/21/2025* FEI NUMBER 3011429437

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ehab M. Amin, Quality Manager

FIRM NAME	STREET ADDRESS
3D Diagnostix Inc.	24 Denby Rd Ste 148
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allston, MA 02134-1606	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

The design history file was not established.

Specifically,

Your firm failed to follow your Design & Development procedure, Revision D, Section 6.5, Dated 07/26/2022 and Revision C, Section 6.5 Dated 03/20/2019 which requires creating a design history file for your devices.

A. Your firm has not established a design history file or have records of a design plan, design inputs, design outputs, design verification, design validation design reviews or design transfer for your class II Nightguard intended to alleviate the pain and damage caused by bruxing or clenching the teeth.

B. Your firm has not established a design history file or have records of a design plan, design inputs, design outputs, design reviews or design transfer for your class II iSmile Theromoformed and 3D Printed Aligner. iSmile Aligner is intended and indicated for the alignment of teeth during orthodontic treatment of malocclusion including openbite, deepbite, mild/moderate crowding and generalized spacing.

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EMPLOYEE(S) SIGNATURE
Sunita Pandey, Investigator

X Sunita Pandey
Investigator
Signed By: 2003030873
Date Signed: 11-21-2025
14:56:30

DATE ISSUED
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OBSERVATION 2

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically,

A. You failed to follow your Process Validation Procedure, QSP 7.5-6, Effective Date 12/01/2018 which requires to establish objective evidence when conducting Performance Qualification that the manufacturing process, under anticipated conditions, consistently produces a product which meets all predetermined requirements, and as per your 3D Printers Performance Qualification protocol, PQP.001, Rev D, Dated 10/11/2023, all 3D printers are required to be revalidated (b) (4) . Your most recent 3D printing process validation test, "PQP.001 REV: D, 3D Printers Performance Qualification Report, Dated 03/18/2025" intended to ensure the quality and reliability of the 3D printing from your (b) (4) 3D Printers used to manufacture your medical devices including Class II iSmile Dental Aligners, Class II Night Guard and Class I Surgical Guide; however, the validation failed to perform with the highest degree of assurance.

I. While the protocol tests basic printing capabilities using a standardized (b) (4) as a sample, it does not provide documented justification for how the (b) (4) sample adequately represents all the medical devices you manufacture using these printers including Class II dental aligners and Class II night guards. The validation also failed to justify why the (b) (4) sample adequately represents the complexity, tolerances, and critical quality attributes of the actual medical devices being manufactured.

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II. The test methods and results fails to establish how and what printer settings were evaluated and tested, and which printer was used for validating which medical device. The test also failed to identify which specific setting passed that was deemed acceptable and validated the test.

III. The validation test fails to identify essential process validation steps including test methods, worst-case scenario testing, process robustness studies, and demonstration of process capability over time. The test also failed to demonstrate how the acceptance criteria were established.

IV. The validation focuses primarily on final product characteristics (dimensional accuracy, visual features) but fails to identify, monitor, and control critical process parameters such as printing temperature, layer thickness, curing time, resin viscosity, and environmental conditions.

B. Your procedure, section 6.1.2 requires determining if process requires validation and if the output of the process is not verifiable then the decision should be to validate the process as per section 6.1.2.2. However, the sterilizing instruction, (b) (4) sterilization technique, provided to your customer for your Class I surgical Guide who are dental surgeons has not been validated, nor has it been assessed whether the validation is required or not.

OBSERVATION 3

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically,

Your firm failed to adequately investigate complaints and negative feedback as per your complaint handling procedure, QSP 8.2-1, Rev C, Dated 01/20/2023 and Feedback procedure QSP 8.2-3, Rev C, Dated 05/07/2024 per the following:

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A. Your firm failed to adequately assess medical device reportability for received complaints and negative feedback for your Class II iSmile Dental Aligner. Your firm failed to adequately assess Form 8.2-1-3 Adverse Event Determination Sheets as required by your procedure for 3 of 4 reviewed complaints for your Class II aligners in 2023, 2024 and 2025. Three reviewed complaints identified the device issue during the use, yet no investigation to assess MDR reportability was performed and were simply assessed without justification documented. Furthermore, 2 of these were not investigated at all and one was closed by stating the trays were inspected before the distribution.

B. The firm does not handle all negative feedback as complaints and therefore does not perform MDR assessments or formal investigations for all reported product deficiencies. Per QSP 8.2-3, Rev C, Effective 05/07/2024, Section 6.8, negative feedback categorized as "Clinical Error or Inconclusive" is not recorded as complaints despite your procedure defining complaints as "any communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, performance, labelling or packaging of a device." Additionally, your MDR procedure, QSP 9.1-3 Medical Device Reporting, Rev B, Effective 12/01/2018 requires to report user error as well. With at least 1,400 negative feedback entries received in 2023, 2024, and 2025, there is no evidence these were assessed for MDR reportability and were identified later as complaint.

OBSERVATION 4

Procedures for corrective and preventive action have not been adequately established.

Specifically,

A. Your firm failed to follow your CAPA procedure QSP 8.5-1 Rev B, Dated 08/01/2018 which requires proper risk assessment and categorization of Corrective and Preventive Actions based on the severity and regulatory impact of identified issues. Your procedure defines Major CAPAs as "significant violation of quality policy, regulatory requirement or product integrity" requiring

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response within (b) (4), yet your firm incorrectly categorized CAPA 25-006, involving Unique Device Identification (UDI) noncompliance for all your medical devices including Class II Nightguards and Class II Aligners, was categorized as Minor CAPA when it should have been classified as Major per your procedure.

B. CAPA 25-006 was initiated on 06/16/2025 as the firm has not been printing the UDI label on their shipped devices. Your CAPA List 2025-Form 8.5-1-1 identifies the corrective and preventive action were completed on 09/19/2025 and the target date for effectiveness check as 10/31/2025. However, your CAPA record fails to identify the implementation of corrective actions and verification of effectiveness check. 9 DHRs initiated since 09/19/2025 for your Class II Nightguard did not have UDI implemented and your Quality Manager stated the UDI was implemented around the week of 11/12/2025 only; yet the CAPA did not identify the recent implementation.

C. Your firm failed to follow your CAPA procedure, which requires CAPAs for process non-conformances and problems identified with the Quality Management System, but lacks adequate objective criteria for determining when CAPAs must be initiated. For example, your firm identified that quality acceptance forms before the release were not used for your Class II nightguard until July 2025, yet no CAPA was initiated without a justification. Additionally, on 09/29/2025, your firm identified a nonconformance showing at least 6 months of non-monitoring of temperature despite your environmental control procedure, Rev F and Rev G requiring to monitor the temperature and nightguard production process Rev D, effective 02/25/2021 requiring (b) (4) temperature logging, yet no CAPA was initiated.

OBSERVATION 5

Procedures to control environmental conditions have not been adequately established.

Specifically,

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Your production and work environment procedure QSP 6.3-1, Rev F, Effective 04/04/2023 and Rev G, Effective 11/06/2025 are inadequate for monitoring the production environment as Routine cleaning schedules, cleaning schedule form (6.3-1-1), non-scheduled cleaning documentation, special cleaning techniques, and cleaning personnel training requirements were removed from your procedure effective from 04/04/2023 and reduced to general cleanliness guidelines requiring the firm to "maintain control over cleanliness". As a result, your manufacturing area for Class II Nightguards and Class I Surgical Guides were found to be under insanitary conditions during the walkthrough inspection on 11/10/2025. The water sink identified to be used in the manufacturing process of class I Surgical Guide production area, which also had production knives in it was found to be clogged, covered with filth, and apparent mold without being identified as out of service. Additionally, the printers and bins which are used in manufacturing your Class II Nightguards were covered with dust and stains. Also, you failed to recognize the temperature was not being monitored for about 6 months until 09/29/2025 in your 3D printing production area as required by your procedure.

OBSERVATION 6

Procedures for device history records have not been adequately established.

Specifically,

You failed to follow your Device History Record, QSP 7.5-1, Dated 10/25/2022 per the following:

A. 10 of 10 reviewed DHRs for class II Nightguard shipped from 11/27/2024 to 10/28/2025 did not include or refer to the location of unique device identifier (UDI) and did not have primary product label and labeling including instruction for use as required by your Device History Record procedure, section 6.5.

B. 4 of 10 did not have any record of the quality acceptance as required by Night Guard Production

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Process procedure, WI-21, Rev D, Effective 03/30/2021, Section g and as required by section 6.5.8 of your DHR procedure, and 1 of 6 which used quality check form, (DHR 581587), did not check the required quality criteria. Additionally, procedure WI-21, section requires o use WI-21-2, batch record form which tracks the printer and material used; however, 10 of 10 rereviewed DHRs did not use the form and therefore failed to demonstrate the devices were manufactured as per DMR.

OBSERVATION 7

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

Specifically,

A. The firm's acceptable suppliers are not adequately maintained as 2 of 2 current suppliers for class II Nightguard were not identified in the current approved supplier list, Rev G as required by your supplier evaluation and monitoring procedure, Rev G, Dated 02/26/2024. 1 of 2 provides all the critical components that has been changed since 08/21/2024 while the other one supplies resin that is used in inspecting your Nightguard.

B. Your supplier evaluation and monitoring procedure, Rev G, Dated 02/26/2024 procedure fails to establish supplier change notification requirement for Class B suppliers, which are medical device suppliers but not designed specifically for 3DDX, as a result none of your class B suppliers including modeling resin suppliers, magnet and glue suppliers did not have a change notification agreement established. As per your procedure, section 6.3.2, class A suppliers are required to have a quality agreement established which includes change notification agreement; however, 2 of 4 reviewed Class A suppliers did not have this quality agreement established nor did have a justification, of which 1 provides all the changed critical components to your class II nightguard and the other one provides resin used in your medical devices.

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C. The supplier evaluation procedure establishes a scoring system using ratings of (b) (4) ((b) (4), (b) (4)) for four evaluation criteria including quality of products and services for both Class A and Class B suppliers, but fails to provide objective, measurable criteria or definitions for when each rating should be applied. This deficiency is evidenced by inconsistent evaluation outcomes where your Class A supplier for Class II Aligners received identical quality performance scores of (b) (4), (b) (4) and total scores of (b) (4)% in both 2023 and 2024, despite having 6 NCRs initiated in 2023 and 2 additional NCRs for repeat issues in 2024, with no further actions required in either evaluation period as per the procedure.

OBSERVATION 8

Procedures for acceptance of incoming product have not been adequately established.

Specifically, your Receiving Inspection procedure, QSP 7.4-3 Rev E, Dated 08/15/2022 requires performing receiving inspection and inspections as defined in the Receiving Inspection Requirements List (Form 7.4-3-2), however, the receiving inspection for your critical component, resin, used in your Class II Night guard manufacturing, failed to identify the inspection was performed as per the procedure with an objective evidence. For example, Form 7.4-3-2 was provided as the only receiving inspection for the resin received through PO02076 where manufacturing/expiry date, received quantity, and visual inspection are simply identified as "True" without specifying what "True" and "False" designations represent, no objective evidence was provided to show what specific expiry dates were verified, what visual characteristics were inspected, or what quality checks and additional inspection to ensure product meets design inspection were verified as required by section 6.2.3 and 6.2.4 as required by the procedure.

***DATES OF INSPECTION**

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11/10/2025(Mon), 11/12/2025(Wed), 11/13/2025(Thu), 11/17/2025(Mon), 11/18/2025(Tue), 11/21/2025(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

Observation 6: Promised to correct

Observation 7: Promised to correct

Observation 8: 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."