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	3/3/2026-3/6/2026
	FEI NUMBER 1937100

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Matthew K. Malabey, Vice President of Operations and R&D

FIRM NAME	STREET ADDRESS
Ortho Solutions LC, dba DynaFlex	8050 Hawk Ridge Trail
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lake Saint Louis, MO 63367-2204	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

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically, DynaFlex manufactures and distributes DynaFlex Sleep Apnea and Anti-Snoring Devices, FDA class II medical devices.

DynaFlex's risk analysis classifies the following hazards for these medical device as follows:

i. allergic reactions as (b) (4), involving serious reversible injury potentially requiring invasive procedures.
ii. Patient chokes on or swallows a component of the device as (b) (4), Serious injury (irreversible) or (b) (4) of the patient or user.

I reviewed DynaFlex complaints received from 1/1/2024 thru present. Despite the risk analysis classification and the work instruction requiring risk analysis review during complaint processing, the firm failed to submit MDRs within 30 days for ten (10) complaints reporting allergic reaction (6) and swallowing a component (4).

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: 03-06-2026 12:34:31	3/6/2026

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Examples of the complaints not submitted as MDR's are as follows:

Row	Complaint ID	Aware Date	Device	Complaint
1	1542	3/26/2025	Respire Pink AT - HS	Screw came out in patient mouth while sleeping. Patient swallowed it.
2	1710	6/05/2025	Respire Pink AT	The screw came out as patient was sleeping. May have swallowed the screw.
3	1699	5/29/2025	Slimline 39 RPE	Patient has broken out in hives, sores and possible allergic reaction.
4	1853	7/01/2025	Respire Pink AT	The patient had a negative reaction to the arms of the OA (device) that has caused blistering.
5	1402	10/16/2024	Respire Pink AT Micro - Hard	Patient had an allergic reaction to the acrylic in her Dorsal device. Her mouth was itching around the gum line and after continued use her throat started to swell shut.

The firm's work instruction (WI 82155) requires risk analysis review during complaint processing, yet these complaints were not submitted as MDRs despite meeting the firm's own hazard severity classifications.

OBSERVATION 2

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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, on or about May 15, 2023, your firm acquired the Respire Snoring/Sleep Apnea Product Line.

During the 2023 FDA inspection (dated 09/18/2023 through 9/25/2023) you were advised the Respire product UDI (Unique Device Identification) registrations needed to be updated to reflect the new ownership.

A. As of March 3, 2026, the following products still reflect ownership as Respire Medical Holdings LLC rather than your firm:

Row	Brand Name	UID-DI	510(k)
1	Blue + Hard	00851861007093	K111207
2	Respire Pink+ H/S	00851861007147	K131138
3	Pink Micro	00851861007055	K150572
4	Blue Series - EF	00851861007024	K152292
5	Blue EF + Hard	00851861007116	K152292
6	Respire Pink Series Micro H/S with DentiTrac	00851861007208	K170692
7	Respire Pink AT Hard	00851861007260	K192127

B. On March 3, 2026, a Respire Pink AT Hard device (K192127) bore a QR code label reading "D841;8261R;R444464;3/3/2026". As of March 6, 2026, this code could not be verified as a valid UDI in the GUDID database, and it is unclear whether this represents a UDI-DI or other identifier.

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OBSERVATION 3

Equipment calibration or verification was not performed according to documented procedures.

Specifically, there are (b) (4) primary calipers available at DynaFlex for calibrating the (b) (4) CNC machines. I reviewed the (b) (4) calibration procedure (WI 1919308), CNC owner's manual, calibration records for CNC machine number (b) (4) (CNC (b) (4) and the (b) (4) primary calipers. Each CNC machine must be recalibrated (b) (4) I noted the following:

A. Procedure WI 1919308 for CNC (b) (4) calibration lacks documented acceptance criteria, pass/fail limits, and corrective action procedures for failed calibrations.

B. The calibration standards used to verify CNC machines are inadequate:

   i. Both calipers (b) (4) are calibrated to (b) (4) whereas the CNC owner's manual specifies (b) (4) accuracy requirements

   ii. This represents a calibration standard that is less accurate than the equipment being verified, violating the principle that standards must be more accurate than the equipment being calibrated

C. Caliper (b) (4) was used while (b) (4) overdue for recalibration (due (b) (4) recalibrated (b) (4), and the calibration label displays incorrect dates.

These deficiencies affect the calibration validity of all (b) (4) CNC machines used in production.

OBSERVATION 4

Product which does not conform to product requirements was not identified and controlled to prevent its unintended use or delivery.

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: 03-06-2026 12:34:31	3/6/2026

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Specifically, DynaFlex procedure QSP 7.5-5, Handling, Storage, Packaging & Delivery, requires that expired product be deemed non-conforming and handled according to QSP 8.3-2, Control of Non-Conformances and Rework. QSP 8.3-2 requires (b) (4)
(b) (4)

However, your firm failed to control expired materials according to these procedures as follows:

During the FDA inspection conducted September 18 through 25, 2023, one container of expired modified composite powder and liquid for fabricating clear night guards (expiration date: 01-2018) was identified in materials storage. This was addressed through verbal discussion with management.

On March 3, 2026, I observed (b) (4) of expired (b) (4) additives in materials storage. These bottles, which are used as components in the manufacture of orthodontic medical devices, were labeled with expiration dates ranging from November 2023 through December 2025. The expired materials were not (b) (4) or otherwise controlled to prevent their unintended use.

OBSERVATION 5

Justification for not investigating a complaint(s) was not documented.

Specifically, DynaFlex customer complaint investigation work instruction (WI 82155) documents if no investigation is needed, the reason (justification) is documented.

I reviewed 11 of the 941 complaints DynaFlex received since 1/1/2024. Three (3) of the eleven (11) complaints reviewed were not investigated. There was no documented reason (justification) why an

investigation was not required for these complaints. The complaints without justification were as follows:

Complaint ID	Aware Date	Device	Complaint
1803	8/19/2025	DynaFlex Herbst, (b) (4)	Upper left pivot broke out of acrylic for the second time. Lower right pivot is also rusting mildly.
1465	1/31/2024	Respire Pink AT	Patient swallowed a bracket that broke off from the device.
1173	1/31/2024	Respire Pink AT	Patient woke up with one of the screws missing from their device. They suspect that the patient may have swallowed the screw.

OBSERVATION 6

Procedures for validation of processes did not adequately include defined criteria for review and approval of the processes, equipment qualification and qualification of personnel and use of specific methods, procedures, and acceptance criteria.

Specifically, DynaFlex failed to adequately validate production equipment and ensure inspection, measuring, and test equipment was properly calibrated prior to use.

DynaFlex operates (b) (4) CNC (Computer Numerical Control) (b) (4) machines that manufacture Class II medical devices, including Dorsal & Herbst sleep apnea appliances, from (b) (4)

(b) (4) material. On or about February 2026, the CNC machines underwent validation following relocation within the facility.

The firm's procedure, Equipment Validation Procedure QSP 7.5.6-10, establishes requirements for equipment validation including:

1. Process validation must establish by objective evidence that a process consistently produces a result or product meeting predetermined requirements
    i. Validation performed by qualified personnel with documented qualifications and maintained records
    ii. Demonstration that results are repeatable

2. Equipment Validation Worksheet F 7.5.6-10 includes:
    i. Documentation that equipment has been calibrated prior to qualification, including calibration date and performing firm

A. Review of calibration records for CN (b) (4) and associated calipers revealed deficiencies affecting the calibration validity of the equipment at the time of validation (February 2-5, 2026). The calibration standards used to verify CNC machines are inadequate:
    i. (b) (4) calipers (b) (4) are calibrated to (b) (4), whereas the CNC owner's manual recommends (b) (4) accuracy requirements
    ii. This represents a calibration standard that is less accurate than the equipment being verified, violating the principle that standards must be more accurate than the equipment being calibrated

B. The validation report for CNC (b) (4) failed to document:

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i. The identity of personnel who performed the validation testing

ii. Evidence that validation personnel were qualified to perform the validation

iii. Qualification records for validation personnel

This is contrary to the firm's procedure QSP 7.5.6-10 requirement that validation is performed by qualified personnel with qualification of individual documented and records maintained.

C. The validation report for CNC (b) (4) (approved 2/26/2026) documented manufacturing of (b) (4) different unique device models during the validation study. However, the validation did not demonstrate that the machine could consistently and repeatedly produce the same model.
Specifically, the validation did not include multiple production runs of the same device model to establish repeatability and consistency of the manufacturing process.

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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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Edward E Lockwood, Investigator	X Edward E Lockwood Investigator Signed By: EDWARD E. LOCKWOOD -S Date Signed: 03-06-2026 12:34:31	DATE ISSUED 3/6/2026

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."