DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	3/16/2026-3/24/2026* FEI NUMBER 1017294

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hector E. Miranda, Interim Site Leader

FIRM NAME	STREET ADDRESS
Linvatec Corp. dba ConMed Linvatec	11311 Concept Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Largo, FL 33773-4908	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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

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

Specifically, you failed to apply a risk-based approach to identify and control systemic quality issues, resulting in a chronic pattern of ineffective corrective actions spanning multiple years, failure to integrate quality data from multiple sources (complaints, manufacturing nonconformances, and service reports), and inadequate trending methodology.

You manufacture reusable powered surgical instruments for orthopedic procedures, including the PRO6150 PowerPro Pneumatic Modular Handpiece and Hall Titan battery handpieces. These devices are intended for bone cutting, reaming, drilling, and driving screws in orthopedic, trauma, and total joint arthroplasty procedures. Your Design Failure Modes and Effects Analysis for the Hall Titan battery handpieces (RMD1291102 Rev T) identifies motor and transmission failures resulting in surgical delays (Severity [(b) (4)] and handpiece overheating with potential patient/user burns (Severity [(b) (4)] Your Design Failure Modes and Effects Analysis for the PowerPro Pneumatic Handpieces (DFA17-0023) identifies frozen/locked motor and seized motor bearings failures resulting in surgical delays and handpiece not usable (Severity [(b) (4)] and dirty motor handpiece runs intermittently with potential surgery delays (Severity [(b) (4)]

However, as a manufacturer of these devices you failed to apply a risk-based approach to identify and control systemic quality issues affecting patient safety. Specifically:

1. **Chronic Pattern of Ineffective Corrective Action:**

Your calibration system required four separate Corrective and Preventive Actions (CAPAs) over a three-year

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period to address recurring out-of-tolerance (OOT) investigation delays: CAPA-109, CAPA-199, CAPA-389 (initiated January 31, 2022), and CAPA-673 (initiated October 6, 2024). CAPA-389 was determined to be "not effective" on September 30, 2024, after 2.5 years of implementation. One month later, CAPA-673 was opened, stating: "This CAPA is being opened to reinvestigate the root cause and to explore additional actions to prevent reoccurrence of the issue described in CAPA-389."

2. **Failure to Integrate Quality Data Sources:**

CAPA-652 Investigation documented that approximately 210 defective Motor Assemblies (b) (4) were collected in work centers WC2881/2882 between October 2023 and May 2024 without being recorded as nonconformances. The investigation states: "After interviewing Operators in WC2881/2882, typical fall-out rate appears to be in 70 - 80 percentile, each time PRO6150 production/testing is executed." The investigation concluded: "It is evident that Nonconformance process is not being following, thus creating variance and inaccurate data/count of defective motors."

During the same period, your firm's in-process inspection of motor components identified widespread non-conformances with 100% failure rates for on critical dimensions through special inspection: NC-14675 (Rotors - (b) (4) ; NC-14696 (Cylinders - (b) (4) NC-14697 (End Plates - (b) (4) ; NC-14676 (Shafts (b) (4) and NC-14699 (Vanes - (b) (4)). These documented nonconforming components for burrs, failed dimensional requirement, failed flatness requirements, failed chamfer requirements, and failed parallel requirements.

CAPA-652 Investigation states: "Burs, Debris, and Residue on components have been identified as one of the main issues to Motors locking up during operation, as these deposits/burs would lodge between the Plates and Rotors and ultimately seize the operation."

These component non-conformances were only discovered through special inspection during CAPA-652 investigation, indicating that routine in-process inspection failed to detect 100% failure rates on critical dimensions affecting over (b) (4) from the affected part numbers Rotors – (b) (4) , Cylinders - (b) (4) End Plates - (b) (4) , Shafts - (b) (4) , and Vanes - (b) (4) . These documented nonconforming components for burrs, failed dimensional requirement, components.

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3. **Service records not Linked to Manufacturing Quality Data:**

During the period when 210 motors were collected without NC documentation, field failures occurred and were documented in service records and related complaints:

- CEN-67608 (February 15, 2024): Service Report SVCREQ1049103 documented "MOTOR - LOW SPEED/TORQUE," "CORROSION LIKE DEPOSITS, INTERNAL"
- CEN-77765 (December 16, 2024): Service Report SVCREQ1107962 documented "MOTOR - SEIZED"
- CEN-81892 (April 23, 2025): Service Report SVCREQ1189590 documented "VALVE - STICKING," "MOTOR - CORRODED"

None of these service records or associated complaints were linked to CAPA-652 despite documenting identical failure modes (motor seizure, corrosion, valve sticking). All complaints were classified as Level [(b)(4)] (or Level [(b)(4)] for CEN-81892) and concluded with "no further investigation is required" based on trending analysis stating: "Based on the two-year product history review, there has been no upward trend within the last (b) (4) and the UCL has not been exceeded within the last (b) (4)

These trending conclusions were based on incomplete nonconformance data that failed to capture the 210 undocumented motor failures, the documented 66-70% failure rate occurring during the same period, and the over 1,000 non-conforming components with 100% failure rates on critical dimensions.

4. **Continued Field Failures:**

Field failures continued after CAPA-652 corrective actions were implemented (CAPA-652-A2 implemented January 31, 2025; CAPA-652-A1 implemented May 6, 2025). This was evident in:

- CEN-88863 (November 12, 2025): Three devices with motor issues
- CEN-89657 (November 26, 2025): Fourteen devices including three PRO6150 handpieces with motor seizures, corrosion, and valve failures
- CEN-90304 (December 14, 2025): PRO6150, valve sticking
- CEN-90871 (December 30, 2025): Four PRO6150 handpieces with customer reporting "the power is not enough to operate although the air pressure is good"

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OBSERVATION 2

Corrective action was not adequately taken to eliminate the cause of nonconformities in order to prevent recurrence.

Specifically, your corrective action system demonstrates multiple systemic failures including inadequate review of service data, root cause analyses that stop at symptoms rather than identifying systemic causes, failure to address internal manufacturing quality issues despite identifying non-conforming components with 100% failure rates on critical dimensions, and flawed verification of effectiveness methodologies.

1. **Inadequate Review of Service reports as they relate to customer complaints:**
   Your firm failed to adequately review data from service reports to ensure updated complaint information was documented and properly evaluated. Complaints CEN-67608, CEN-77765, CEN-81892, CEN-88863, CEN-89657, CEN-90304, and CEN-90871 were classified as Level (b)(4) (except CEN-89657 as Level (b)(4) and closed with "no further investigation is required" despite service reports documenting motor seizures, corrosion, valve failures, and bearing damage—the exact failure modes identified in CAPA-652 as having 66-70% occurrence rates.

   Complaint CEN-89657 (November 26, 2025) involved fourteen devices from a single customer. The investigation concluded for each device: "Reported event of the device not working well is inconclusive. The device has not been returned to date and photographic evidence was not provided. Therefore, the reported event cannot be verified." However, service reports were available for twelve of the fourteen devices documenting motor seizures (SVCREQ1173722), motor corrosion (SVCREQ1173721, SVCREQ1173704), bearing damage (SVCREQ1173696, SVCREQ1173702, SVCREQ1173706, SVCREQ1173711), and controller failures (SVCREQ1173683, SVCREQ1173713).

2. **Inadequate Review of Manufacturing Nonconformities:**
   Your firm failed to adequately review and address internal manufacturing quality issues. Five nonconformance reports documented over 1,000 non-conforming motor components manufactured in-house with 100% failure rates on critical dimensions:
   - **NC-14675 (Rotors):** All (b) (4) samples (100%) had burrs; four of seven had dimensional failures ((b) (4) parts total)

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- **NC-14696 (Cylinders):** All (b) (4) samples (100%) failed dimensional requirements (b) (4) parts total)
- **NC-14697 (End Plates):** All (b) (4) samples (100%) failed flatness requirements (b) (4) parts total)
- **NC-14676 (Shafts):** All (b) (4) samples (100%) failed dimensional and (b) (4) requirements
- **NC-14699 (Vanes):** Dimensional and parallel failures (b) (4) parts total)

CAPA-652 Investigation states: "Burs, Debris, and Residue on components have been identified as one of the main issues to Motors locking up during operation." Despite this, each NC concluded "no CAPA required" or "Part risk is low, and no trend was identified therefore, no further escalation required." No investigation was initiated to determine why manufacturing processes produced 100% failure rates, and the (b) (4) total non-conforming components were released to production and used in motor assemblies.

OBSERVATION 3

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

Specifically, you failed to identify and control nonconforming product during manufacturing, resulting in approximately 210 defective Motor Assemblies being collected between October 2023 and May 2024 without being recorded as nonconformances, and failed to implement adequate containment when nonconforming product was identified. Despite acknowledging that defective motors were shipped outside of United States (OUS) repair centers, no evidence was provided of field notifications, stock audits at (b) (4) repair centers in multiple countries, or recall evaluation. Field failures from February 2024 through December 2025 confirm that defective motors reached OUS locations and were used in PRO6150 handpieces.

1. **Failure to Identify and Document Nonconforming Product - Motor Assemblies:**

CAPA-652 Investigation states: "Furthermore, defective motors have been collected in WC2881/2882 without being recorded as Non-conformance, for a long period of time." The investigation documented approximately 210 defective Motor Assemblies (b) (4)) collected between October 2023 and May 2024 without being identified as nonconformances. The investigation concluded: "It is evident that Nonconformance process is not being followed, thus creating variance and inaccurate data/count of defective motors."

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2. Failure to Identify and Control Nonconforming Product - Motor Components:
Your firm failed to identify and control nonconforming motor components during manufacturing. Over 1,000 non-conforming components with 100% failure rates on critical dimensions were released to production: NC-14675 (Rotors - (b) (4) ; NC-14696 (Cylinders - (b) (4) ; NC-14697 (End Plates - (b) (4) NC-14676 (Shafts - (b) (4) , and NC-14699 (Vanes - (b) (4) .

These component non-conformances were only discovered through special inspection during CAPA-652 investigation, indicating that routine in-process inspection failed to detect 100% failure rates on critical dimensions affecting 1,035 total components. Despite these findings, each NC concluded "no CAPA required" or "Part risk is low, and no trend was identified therefore, no further escalation required," and the non-conforming components were released to production for use in motor assemblies. CAPA-652 Investigation explicitly states that these component non-conformances "would contribute to Motors locking up during operation."

3. Inadequate Containment:
CAPA-652 Risk/Containment states: "No further containment required beyond the containment performed within the associated NCs." However, CAPA-652 Investigation (Attachment 03, page 3) states: "Identified gap in Manufacturing process of non-existent Inspection process to confirm function of the motor has been identified as major issue as it introduces unverified motors to Production floor in Largo manufacturing, as well as any (b) (4) Repair centers."

The investigation acknowledged defective motors were shipped to (b) (4) repair centers, yet no evidence was provided of field notifications, stock audits at (b) (4) repair centers, or recall evaluation. Field failures confirm defective motors reached (b) (4) locations (b) (4)

OBSERVATION 4
Production and service provision was not adequately planned, carried out, monitored, and controlled to ensure that product conforms to specification.

Specifically, your manufacturing processes for motor components (rotors, cylinders, end plates, shafts, vanes) produced over 1,000 non-conforming components with 100% failure rates on critical dimensions, yet routine in-

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process inspection failed to detect these non-conformances. Additionally, your firm failed to adequately control these manufacturing processes and prevent release into manufacturing of known nonconforming parts.

1. **In-Process Inspection Failed to Detect Component Non-Conformances:**

Your firm's routine in-process inspection failed to detect widespread component non-conformances with 100% failure rates on critical dimensions. Over 1,000 non-conforming motor components were released to production before being identified through special inspection during CAPA-652 and documented in: NC-14675 (Rotors - (b) (4)); NC-14696 (Cylinders - (b) (4) NC-14697 (End Plates - (b) (4) ; NC-14676 (Shafts (b) (4) and NC-14699 (Vanes - (b) (4)).

CAPA-652 Investigation documents detailed inspection results showing that these component non-conformances directly contribute to motor failures.

2. **Failure to Control Manufacturing Processes:**

Your firm failed to implement adequate production controls to prevent manufacture of non-conforming components. The fact that 100% failure rates on critical dimensions were not detected until special inspection during CAPA-652 investigation indicates:

- Routine in-process inspection is inadequate to detect critical dimensional failures, burrs, and flatness deviations
- Manufacturing processes are not capable of consistently producing components within specification
- Process controls do not prevent release of components with 100% failure rates

Despite each NC concluding "no CAPA required," no investigation was initiated to determine:

- ☐ Why manufacturing processes produced 100% failure rates on critical dimensions
- ☐ Why routine in-process inspection failed to detect these non-conformances
- ☐ What process changes are needed to prevent recurrence
- ☐ Whether manufacturing processes require validation or revalidation

OBSERVATION 5

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Information gathered in the feedback process does not adequately serve as potential input into risk management for monitoring and maintaining product requirements as well as the product realization or improvement processes.

Specifically, your firm failed to gather and analyze service report data as post-production feedback, failed to use this data to provide early warning of quality problems, and closed complaints without adequate investigation despite service reports documenting significant product defects.

Your firm failed to analyze service report data with appropriate statistical methodology. Your Customer Service Repair Authorizations procedure (SI-000-442 Rev AL) provides instructions for processing repairs but does not require analysis of service report data for trends, trending of service codes, statistical analysis of component replacements, or integration with complaint or CAPA systems.

Service reports from February 2024 through December 2025 documented motor failures, valve failures, and corrosion (CEN-67608: "MOTOR - LOW SPEED/TORQUE," "CORROSION LIKE DEPOSITS, INTERNAL"; CEN-77765: "MOTOR - SEIZED"; CEN-81892: "MOTOR - CORRODED," "VALVE - STICKING"; CEN-89657: twelve service reports documenting motor seizures, corrosion, bearing damage). These findings were not analyzed for trending with manufacturing nonconformances, linked to CAPA-652 investigation, or used as input to risk management.

***DATES OF INSPECTION**
3/16/2026(Mon), 3/17/2026(Tue), 3/18/2026(Wed), 3/19/2026(Thu), 3/20/2026(Fri), 3/23/2026(Mon), 3/24/2026(Tue)

X Lorraine N Williams
Investigator
Signed By: LORRAINE N. WILLIAMS -S
Date Signed: 03-24-2026 18:03:16

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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

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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."