DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	3/16/2026-3/20/2026
	FEI NUMBER 3030088168

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joshua S. Pelz, CEO

FIRM NAME	STREET ADDRESS
Limber Prosthetics and Orthotics, Inc	4883 Ronson Ct Ste G
CITY, STATE, ZIP CODE, COUNTRY San Diego, CA 92111-1812	TYPE ESTABLISHMENT INSPECTED 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 I OBSERVED:

OBSERVATION 1

Quality management system software was not validated.

Your firm did not validate software used in the design and manufacture of Class II Limber Unileg prosthetic limb as required by

- Procedure titled: Design Verification and Validation Procedure, Doc#: QSP-037, Rev: A.0, Effective date:6/1/2023, section 5.8.
- Procedure titled: Process Validation Procedure, Doc#: QSP-076, Rev: A.0, Effective date: section 9.1.

Specifically:
1. LimberClinical iOS Application (Version 3.31)
The software is used to transfer patient-specific data for manufacturing was not validated. This application transfers the following critical data:

- 3D scans and measurements of the patient's limb or existing prosthesis (weight, height, foot length)
- Prosthetic alignment information (range of motion, heel height, contractures)
- Clinical notes (suspension method, socket design requests)
- Order placement information

These data are directly used in the manufacture of the device.

2. Off-the-Shelf Software Used in Manufacturing
The following (b) (4) software applications used in the manufacturing process were not

AMENDMENT 1

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	Juanj Wu, Investigator X Juanj Wu Investigator Signed By: 2001334541 Date Signed: 03-20-2026 12:56:27	3/20/2026

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validated:

(b) (4)

OBSERVATION 2

Outsourced processes that affect product conformity to requirements were not adequately monitored and controlled.

Specifically, your firm outsourced the coating process for the Class II Limber Unileg prosthetic limb. However, the following deficiencies were observed:

1. Unapproved Supplier

The contract manufacturer performing the coating process was not listed on your firm's Approved Supplier List, as required by your firm's procedure titled: Purchasing Controls and Prequalifying Audits Procedure, Document #:QSP-050, Rev: B, Effective date: 6/1/2023, Section 7.1 of this procedure requires that approved vendors be recorded on the Approved Vendor List.

2. Lack of Vendor Evaluation Records

Your firm was unable to provide vendor evaluation records for this contract manufacturer, as required by your firm's procedure titled: Purchasing Controls and Prequalifying Audits Procedure, Document #:QSP-050, Rev: B, Effective date: 6/1/2023, Section 4.3 of this procedure requires that all vendor qualification records be maintained by the Quality Department.

3. Absence of Quality Agreement

Your firm was unable to provide a quality agreement with this contract manufacturer, as required by your firm's procedure titled: Purchasing Controls and Prequalifying Audits Procedure, Document #:QSP-050, Rev: B, Effective date: 6/1/2023, Section 7.2 of this procedure requires that written agreements be made between Limber Prosthetics & Orthotics and vendors as necessary for quality

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control.

4. Missing Process Validation Documentation
Your firm was unable to provide validation records for the coating process performed by the contract manufacturer. Your firm's CAPA-0001 linked three complaints investigation identified coating process nonconformance. According to your firm's procedure titled: Process Validation Procedure, Doc#: QSP-076, Rev: A.0, Effective date: 6/1/2023. The coating process needs to be validated.

OBSERVATION 3
The correct unique device identifier (UDI) information regarding was not provided to the FDA via the Global Unique Device Identification Database (GUDID).

Specifically, your firm's Class II Limber Unileg prosthetic limb bears a Unique Device Identifier (UDI) on its label. However, when this UDI was searched in FDA's GUDID, no record was found for this device during the inspection.

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Annotations to Observations

Observation 1: Under consideration

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."