

Alphatec Holdings, Inc.
Form 8-K
July 23, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported):
July 17, 2015

ALPHATEC HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

DELAWARE (State or other jurisdiction of incorporation)	000-52024 (Commission File Number)	20-2463898 (IRS Employer Identification No.)
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5818 El Camino Real
Carlsbad, CA 92008
(Address of principal executive offices) (Zip Code)

(760) 431-9286
Registrant's telephone number, including area code:

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

On July 17, 2015, Alphatec Spine, Inc. (the “Company”), a wholly owned subsidiary of Alphatec Holdings, Inc., received a Warning Letter, dated July 16, 2015, from the U.S. Food and Drug Administration (the “FDA”) in connection with the FDA’s inspection of the Company’s manufacturing facilities located in Carlsbad, CA that occurred from February 4, 2015 until March 13, 2015 (the “Inspection”).

In the Warning Letter, the FDA cited eight deficiencies in the Company’s responses to the FDA Form 483, Inspectional Observations, which was issued to the Company at the end of the Inspection. The deficiencies relate to the Company’s internal procedures for quality planning, design control, document control and corrective and preventive actions.

The Warning Letter does not restrict production or shipment of the Company’s products from its facilities, or the sale or marketing of the Company’s products. The Company is currently addressing the deficiencies cited by the FDA in the Warning Letter and intends to work closely with the FDA to resolve any outstanding issues. Until the procedures noted in the Warning Letter are corrected, the Company may be subject to additional regulatory action by the FDA, and any such actions could significantly disrupt the Company’s ongoing business and operations and have a material adverse impact on the Company’s financial position and operating results. There can be no assurance that the FDA will be satisfied with the Company’s response. The Warning Letter will be posted on the FDA’s website at www.fda.gov and, once posted, will be available for viewing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALPHATEC HOLDINGS, INC.
(Registrant)

Date: July 23, 2015

/s/ Eburn S. Garner, Esq.
Eburn S. Garner, Esq.
General Counsel and Senior Vice President