

Alphatec Holdings, Inc.
Form 8-K
July 01, 2010

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): June 25, 2010

ALPHATEC HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of incorporation)

000-52024
(Commission File Number)
5818 El Camino Real

20-2463898
(IRS Employer Identification No.)

Carlsbad, CA 92008

(Address of principal executive offices) (Zip Code)

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(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 June 25, 2010, Alphatec Spine, Inc. (the Company), a wholly owned subsidiary of Alphatec Holdings, Inc. (the Parent) received a warning letter, dated June 21, 2010, 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.

In the warning letter, the FDA cited deficiencies in the response letter sent by the Company to the FDA following the Form 483, List of Investigational Observations, which was delivered to the Company in connection with the inspection that occurred from January 20, 2010 until February 11, 2010. These deficiencies are related to the Company's internal procedures for design controls, complaint handling and medical device reporting. The existence of the outstanding Form 483 letter was disclosed in the Business Section and the Risk Factors of the Parent's Annual Report on Form 10-K for the year ended December 31, 2009.

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 warning letter does not require the Company to recall any of its 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 items raised 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 Parent'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 1, 2010

/s/ Eburn S. Garner, Esq.
Eburn S. Garner, Esq.

General Counsel and Vice President