NUVASIVE INC
Form 8-K
March 18, 2013

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): March 13, 2013

NUVASIVE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-50744**	**33-0768598**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

7475 Lusk Boulevard, San Diego, California 92121

(Address of principal executive offices, with zip code)

(858) 909-1800

(Registrant s telephone number, including area code)

n/a

(Former name or former address, if changed since last report)

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 March 13, 2013, NuVasive, Inc. (the Company) received a warning letter dated March 12, 2013 from the U.S. Food and Drug Administration (the FDA) related to an inspection of the Company s San Diego, California facility that occurred from October 29, 2012 through November 2, 2012. The inspection did not result in any 483 observations and the warning letter does not cite any quality system concerns.

The FDA letter identifies specific labeling claims related to the Company s ILIF procedure, indicating that one of the indications noted is not cleared through any of the Company s Affix Spinous Process Plate system 510(k)s. The letter only relates to this promotional claim and the Company does not anticipate a disruption in the distribution of these products.

The Company takes this matter seriously and has already begun to respond to the FDA s requests. The Company is giving the matter the highest priority in order to fully address the FDA s concerns to our mutual satisfaction. As this is an administrative process to address the warning letter, the Company believes the FDA s concerns can be resolved without an impact on the Company s financial results or operations.

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.

NUVASIVE, INC.

Date: March 18, 2013

By: /s/ Jason Hannon
Jason Hannon
Executive Vice President, General Counsel