

TRANSENERIX INC.
Form 8-K
April 20, 2016

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):

April 20, 2016

TransEnterix, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

0-19437

(Commission
File Number)

11-2962080

(I.R.S. Employer
Identification No.)

635 Davis Drive, Suite 300, Morrisville, North
Carolina

27560

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

919-765-8400

Not Applicable

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:

- ☐ 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))

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Item 8.01 Other Events.

On April 20, 2016, TransEnterix, Inc., a Delaware corporation (the "Company") announced that the United States Food and Drug Administration ("FDA") notified the Company on April 19, 2016 that the FDA has determined that the SurgiBot™ System does not meet the criteria for substantial equivalence based upon the data and information submitted by TransEnterix in its 510(k) submission.

The Company's press release is attached as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

Exhibit No. Description

99.1 Press release, dated April 20, 2016

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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.

TransEnterix, Inc.

April 20, 2016

By: /s/ Joseph P. Slattery

Name: Joseph P. Slattery

Title: Executive Vice President and CFO

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Exhibit Index

Exhibit No.	Description
99.1	Press Release dated April 20, 2016