

MERIT MEDICAL SYSTEMS INC

Form 8-K

June 22, 2017

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 22, 2017

Merit Medical Systems, Inc.

(Exact name of registrant as specified in its charter)

Utah 0-18592 87-0447695
(State or other jurisdiction of (Commission (I.R.S. Employer
incorporation or organization) File Number) Identification No.)

1600 West Merit Parkway
South Jordan, Utah 84095
(Address of principal executive offices) (Zip Code)

(801) 253-1600
(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:

- ☐ 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

- ☐ Emerging growth company

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If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On June 22, 2017, Merit Medical Systems, Inc. (the "Company") issued a press release announcing that it has received 513(f)(2) (de novo) classification from the U.S. Food & Drug Administration to expand the indication of the Company's Embosphere® Microspheres to include prostatic artery embolization for symptomatic benign prostatic hyperplasia.

The information in this Current Report on Form 8-K (including the exhibit attached hereto) is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release, dated June 22, 2017, entitled "Merit Medical's Embosphere® Microspheres Receive FDA 513(f)(2) (de novo) Classification for Prostatic Artery Embolization Indication".

SIGNATURES

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

MERIT MEDICAL SYSTEMS, INC.

Date: June 22, 2017 By: /s/ Brian G. Lloyd
Brian G. Lloyd
Chief Legal Officer and Corporate Secretary

EXHIBIT INDEX

EXHIBIT NUMBER DESCRIPTION

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