IRADIMED CORP
Form 8-K
April 01, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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 1, 2016**

IRADIMED CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-36534	**73-1408526**
(Commission File Number)	(IRS Employer Identification No.)
1025 Willa Springs Dr., Winter Springs, FL	**32708**
(Address of Principal Executive Offices)	(Zip Code)

(407) 677-8022

(Registrant s Telephone Number, Including Area Code)

(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 April 1, 2016, IRADIMED CORPORATION (the Company) issued a press release announcing that it had received a letter dated March 23, 2016 via email that its 510(k) application was denied with a finding of non-substantial equivalence. This finding was due to a lack of human factors data demonstrating that its Dose Errors Reduction System (DERS) was adequately validated and that it may resubmit a new 510(k) application with data showing our infusion pump to be substantially equivalent to similar devices in the market. Specifically, the agency stated that two of fifty-six test subjects in the Company s human factors tests unintentionally bypassed the DERS feature, thus avoiding the DERS hard dose limits that healthcare institutions can program into the Company s MRI compatible MRidium 3860+ infusion pumps. The Company intends to appeal this determination to a higher level within the agency. The Company anticipates submitting its appeal to the FDA by April 23, 2016.

The Company also announced that it will release its first quarter 2016 financial results before the market opens on Friday April 29th. The Company will also host a conference call the same day beginning at 11:00 a.m. Eastern Time to discuss those results and to answer questions.

The full text of the press release is included in Exhibit 99.1 to this report.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press release dated April 1, 2016

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.

IRADIMED CORPORATION

Date: April 1, 2016

By:	/s/ Chris Scott
Name:	Chris Scott
Title:	Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Document
99.1	Press release dated April 1, 2016