IRADIMED CORP
Form 8-K
June 09, 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): **June 9, 2016**

IRADIMED CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-36534 (Commission File Number)	**73-1408526** (IRS Employer Identification No.)
1025 Willa Springs Dr., Winter Springs, FL (Address of Principal Executive Offices)	**32708** (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 June 9, 2016, IRADIMED CORPORATION (the Company) issued a press release announcing that it had received the FDA s written response to its appeal of the their determination that the Company s 510(k) application for the MRidium 3860+ MRI compatible IV infusion pump was not substantially equivalent to its predicate device. The FDA has now reinstated the subject 510(k) and has granted the Company another 180 days to make certain specified changes to several messages displayed by the infusion pump. Specifically, changes to messages the infusion pump displays to clarify whether the Dose Error Reduction System is active or inactive and to better describe the over and under range indications. Further, the FDA s response also stated that no additional human factors usability testing is required. The Company intends to revise the messages identified by the FDA, consistent with the agency s explicit recommendations, and submit the required additional information within the 180 day period as prescribed in the FDA s response.

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 June 9, 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: June 9, 2016

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

EXHIBIT INDEX

Exhibit No.	Document
99.1	Press release dated June 9, 2016