IRADIMED CORP
Form 8-K
January 22, 2019

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): **January 22, 2019**

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)

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 (*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))

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 x

Item 8.01 **Other Events.**

On January 22, 2019, IRADIMED CORPORATION (the Company) issued a press release announcing that it temporarily suspended sales of its 3880 MRI compatible patient vital signs monitoring systems in European Commission (EC) markets due to the expiration of its CE Mark on January 17, 2019.

Our products are regulated in Europe by the U.K. Notified Body, UL International Ltd. (UL), who provides Certification allowing use of the CE Mark and permitting shipments of products into EC markets. Maintaining Certification and use of the CE Mark requires manufacturers to routinely undergo periodic re-certification, which typically involves the re-review of a product technical file. Our 3880 MRI compatible patient vital signs monitoring system, originally cleared by UL and added to our EC Certificate in June 2017, was recently subjected to such re-review.

On January 16, 2019, we were notified by UL that their recent technical file review of our 3880 MRI compatible patient vital signs monitoring system could not be completed as aspects of clinical evaluation reporting, as required by newly issued guidance from the European Union, was not acceptable, resulting in a technical non-conformity. Accordingly, UL is issuing a temporary EC Certificate that excludes our 3880 patient vital signs monitoring system. This temporary EC Certificate will extend for six months, during which time we expect to cure the non-conformity and be permitted to again use the CE Mark on our 3880 patient vital signs monitoring system. In full compliance with this notification, we immediately suspended shipments of our 3880 patient vital signs monitor to all markets requiring a CE Mark.

Key points to note resulting from the notification and subsequent temporary suspension of shipments include:

- This action is not the result of safety, effectiveness or performance issues with our 3880 patient vital signs monitoring system.
- This action does not impact sales of our 3880 patient vital signs monitoring system in the U.S. or in other markets that do not require a CE Mark for importation purposes.
- This action does not impact shipments of our MRI compatible IV infusion pump and related accessories, disposables or services.

Forward-Looking Statements

This Current Report on Form 8-K includes forward-looking statements as defined in the Private Securities Litigation Act of 1995, particularly statements regarding our expectations, beliefs, plans, intentions, future operations, financial condition and prospects, and business strategies. These statements relate to future events or our future financial performance or condition and involve unknown risks, uncertainties and other factors that could cause our actual results, level of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. The risks and uncertainties referred to above include, but are not limited to, risks associated with the Company s ability to receive an EC Certificate or CE Mark for our existing products, receive FDA 510(k) clearance for new products; unexpected costs, delays or diversion of management s attention associated with the design, manufacture or sale of new products; the Company s ability to implement successful sales techniques for existing and future products and evaluate the effectiveness of its sales techniques; additional actions by or requests from the FDA; our significant reliance on a single product; unexpected costs, expenses and diversion of management

attention resulting from the FDA warning letter; potential disruptions in our limited supply chain for our products; a reduction in international distribution; actions of the FDA or other regulatory bodies that could delay, limit or suspend product development, manufacturing or sales; the effect of recalls, patient adverse events or deaths on our business; difficulties or delays in the development, production, manufacturing and marketing of new or existing products and services; changes in laws and regulations or in the interpretation or application of laws or regulations.

Further information on these and other factors that could affect the Company s financial results is included in filings we make with the Securities and Exchange Commission from time to time. All forward-looking statements are based on information available to us on the date hereof, and we assume no obligation to update forward-looking statements.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.	**Document**
99.1	Press Release dated January 22, 2019

EXHIBIT INDEX

Exhibit No.	Document
99.1	Press Release dated January 22, 2019.

SIGNATURES

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

IRADIMED CORPORATION

Date: January 22, 2019

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