

Covidien plc  
Form 8-K  
March 14, 2011

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, DC 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the**  
**Securities and Exchange Act of 1934**

**Date of Report (Date of earliest event reported): March 14, 2011**

**COVIDIEN PUBLIC LIMITED COMPANY**

**(Exact Name of Registrant as Specified in Charter)**

**Ireland**  
**(State or Other Jurisdiction**  
  
**of Incorporation)**

**001-33259**  
**(Commission**  
  
**File Number)**

**98-0624794**  
**(I.R.S. Employer**  
  
**Identification No.)**

Edgar Filing: Covidien plc - Form 8-K

**20 on Hatch, Lower Hatch Street**

**Dublin 2, Ireland**

**(Address of Principal Executive Offices, including Zip Code)**

**+353 1 438-1700**

**(Registrant's telephone number, including area code)**

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):

- .. 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))

**Item 7.01. Regulation FD Disclosure.**

Following a meeting with the Data Safety Monitoring Board (DSMB) overseeing the SWIFT (Solitaire FR With Intention For Thrombectomy) Investigational Device Exemption trial, the DSMB recommended that Covidien stop enrolling patients and take the trial data to the U.S. Food and Drug Administration (FDA). The trial includes Covidien's SolitaireFR Flow Restoration device and we are seeking FDA clearance to utilize Solitaire FR to restore blood flow in patients with acute ischemic stroke within eight hours of symptom onset. We will continue to conduct follow-up with the patients already enrolled in the trial. Covidien is collaborating with the FDA with respect to next steps, and we anticipate moving forward with the 510(k) process (the clearance process for medical devices that are substantially equivalent to other legally marketed devices) once the FDA has completed its review of the data.

**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.

COVIDIEN PUBLIC LIMITED COMPANY

By: /s/ John W. Kapples  
John W. Kapples  
Vice President and Corporate Secretary

Date: March 14, 2011