Closer Look

MEMORANDUM

Medtronic issues class II recall for MiniMed Paradigm and 530G systems - September 7, 2014

On August 22, the FDA posted a class II voluntary recall of Medtronic MiniMed Paradigm and 530G systems, affecting all Medtronic insulin pump users. According to the post, Medtronic customers have accidentally programmed the pump to deliver the maximum bolus amount, by scrolling down past zero; the company is currently exploring changing the design such that scrolling will stop at zero. The number of reports has been small, with only one report of severe hypoglycemia that resulted in hospitalization. The company sent a letter on March 13 to customers that described the issue and what safety settings will minimize the risk of an accidental programming error. Notably, the page shares that 559,374 Paradigm and 530G systems have been recalled in total, including 444,374 units in US; that represents the majority of Medtronic's installed base by our estimates. As a reminder from Medtronic's 2014 Analyst Day, we approximated the company's worldwide installed base as high as ~700,000 patients (based on metrics shared by management), and given an F1Q15 revenue split of 58% US/42% international, that approximates to ~407,000 patients in the US and 293,000 patients internationally.