Medtronic News

FDA Approves Changes to Manufacturing Process for Covidien's Pipeline™ Embolization Device

DUBLIN, Ireland--(BUSINESS WIRE)--Aug. 21, 2014--

Covidien plc (NYSE: COV) today announced that the U.S. Food and Drug Administration (FDA) has approved changes to the manufacturing process for the polytetrafluoroethylene (PTFE) coating on the delivery wire of the company's Pipeline™ embolization device.

On April 1, 2014, Covidien voluntarily recalled certain lots of Pipeline and Alligator™ retrieval devices on which the PTFE coating applied to the delivery wire could delaminate and detach from the devices. In the months since, Covidien worked with its suppliers to develop and qualify changes to the coating process.

Given the timely resolution, the recall is expected to have only a slight negative effect on sales and earnings in the fourth-quarter of fiscal 2014.

Covidien learned of the PTFE coating issue that led to the recall through its ongoing internal product testing and alerted customers to the recall by letter on April 1, 2014. The company has not received reports at this time of any patient incidents related to this issue.

The core wire of the Alligator device is also coated with PTFE. The same manufacturing process changes to the application of the PTFE coating that were incorporated into the Pipeline device apply to the Alligator device. Covidien also submitted to the FDA a Special 510(k) change in the manufacturing process for the Alligator device.

The Pipeline device is indicated for the endovascular treatment of adults (22 years of age and older) with large or giant wide-necked intracranial aneurysms in the internal carotid artery from the petrous to the superior hypophyseal segments. The Alligator device is intended for use in the peripheral and neuro-vasculature for foreign body retrieval.

About Covidien

Covidien is a global health care leader that understands the challenges faced by providers and their patients and works to address them with innovative medical technology solutions and patient care products. Inspired by patients and caregivers, Covidien's team of dedicated professionals is privileged to help save and improve lives around the world. With more than 38,000 employees, Covidien operates in 150-plus countries and had 2013 revenue of $10.2 billion. To learn more about our business visit www.covidien.com or connect with us on Twitter.

COVIDIEN CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Statements contained in this communication that refer to Covidien's estimated or anticipated future results or other non-historical facts are forward-looking statements that reflect Covidien's current perspective of existing trends and information as of the date of this communication. Forward-looking statements generally will be accompanied by words such as "anticipate," "believe," "plan," "could," "should," "estimate," "expect," "forecast," "outlook," "guidance," "intend," "may," "might," "will," "possible," "potential," "predict," "project," or other similar words, phrases or expressions. It is important to note that Covidien's goals and expectations are not predictions of actual performance. Actual results may differ materially from Covidien's current expectations depending upon a number of factors affecting Covidien's business. These factors include, among others, competitive factors and market conditions in the industry in which Covidien operates; Covidien's ability to obtain regulatory approval and customer acceptance of new products, and continued customer acceptance of its existing products; and the other risks identified in Covidien's periodic filings including its Annual Report on Form 10-K for the fiscal year ended September 27,

2013, and from time to time in Covidien's other investor communications. We caution you that the foregoing list of important factors is not exclusive. In addition, in light of these risks and uncertainties, the matters referred to in Covidien's forward-looking statements may not occur. Covidien undertakes no obligation to publicly update or revise any forward-looking statement as a result of new information, future events or otherwise, except as may be required by law.

Source: Covidien

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