Stryker Issues Statement Regarding FDA Warning Letter

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While Stryker does not normally comment on discussions with the FDA, the Company believes it is obligated to provide additional information to healthcare professionals, providers and patients in light of several media reports that draw erroneous conclusions surrounding the Warning Letter.

Most importantly, the Company does not believe there is any clinical evidence to indicate that the products mentioned in the Warning Letter present a safety issue to patients. Numerous published independent reports validate the long-term clinical performance of these products.

The Company takes these matters very seriously and has been cooperating fully with the FDA to address questions related to the FDA's observations of Stryker's internal process specifications. As part of a comprehensive review of internal processes following the FDA's observations, the Company conducted an investigation into a deviation from its internal specifications and processes for the Trident PSL and Hemispherical Acetabular Cups manufactured in its Cork, Ireland facility.

The internal investigation confirmed that all Trident Acetabular products manufactured in Cork, Ireland, have met all U.S. and international performance standards for sterility and biocompatibility. However, results from that testing indicated that the level of manufacturing residuals in some cases exceeded the Company's internal acceptance criteria. It is important to note this in no way impacts the product's sterility, nor product conformance to U.S. and international biocompatibility standards. As a result of the deviation from internal specifications, the Company is initiating a voluntary recall of Trident PSL and Hemispherical Acetabular Cups manufactured in its Cork facility. Medical expert opinion of current and historical data concludes that there are no safety issues for patients who received these products. In fact, independent clinical evidence confirms that the performance of these cups compares very favorably with other high performing acetabular devices.(1,2,3)

Trident Acetabular Cups manufactured in the Company's Mahwah, New Jersey facility are not part of the voluntary recall and are still available to supply Stryker's customers.

The Company anticipates some short-term supply disruption as a result of this action and is focused on eliminating these disruptions as expeditiously as possible. In that regard, the manufacturing process for these cups in Cork has now been validated, product shipments have resumed and the Company has increased production at both the Mahwah and Cork facilities. Quality is a Stryker core value and the Company remains committed to developing, manufacturing and marketing medical products that are safe and effective and that comply with applicable laws and regulations, including those administered by the FDA and regulatory bodies in other countries in which Stryker conducts business.

The Company does not anticipate any material financial impact on Stryker's guidance for its 2008 results as a result of this voluntary recall. Details regarding the Company's sales and earnings outlook will be provided in conjunction with the release of its fourth quarter 2007 operating results on Wednesday, January 23, 2008.

Forward-Looking Statements

This press release contains information that includes or is based on forward-looking statements within the meaning of the federal securities law that are subject to various risks and uncertainties that could cause the Company's actual results to differ materially from those expressed or implied in such statements. Such factors include, but are not limited to: pricing pressures generally, including cost-containment measures that could adversely affect the price of or demand for the...
Company's products; regulatory actions; unanticipated issues arising in connection with clinical studies and eventual FDA approval of new products; changes in reimbursement levels from third-party payors; a significant increase in product liability claims; changes in economic conditions that adversely affect the level of demand for the Company's products; changes in foreign exchange markets; changes in financial markets; and changes in the competitive environment. Additional information concerning these and other factors are contained in the Company's filings with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q.

Stryker Corporation is one of the world's leading medical technology companies with the most broadly based range of products in orthopaedics and a significant presence in other medical specialties. Stryker works with respected medical professionals to help people lead more active and more satisfying lives. The Company's products include implants used in joint replacement, trauma, craniomaxillofacial and spinal surgeries; biologics; surgical, neurologic, ear, nose & throat and interventional pain equipment; and endoscopic, surgical navigation, communications and digital imaging systems; as well as patient handling and emergency medical equipment. For more information about Stryker, please visit the company web site at www.stryker.com.


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