

FDA Classifies Voluntary ShapeMatch® Cutting Guides Recall as Class I Recall

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Kalamazoo, Michigan - April 10, 2013 - Stryker Corporation (NYSE:SYK) announced today that its orthopaedic division has received notice that the U.S. Food and Drug Administration (FDA) has reviewed the voluntary recall of its ShapeMatch Cutting Guides and that it will be classified as a Class I recall.

ShapeMatch Cutting Guides are intended to be used as patient specific surgical instrumentation to assist in the positioning of total knee replacement components intraoperatively and in guiding the marking of bone before cutting.

In November 2012, Stryker Orthopaedics instructed all U.S. registered ShapeMatch surgeons to discontinue use and ordering of ShapeMatch Cutting Guides and in January 2013 voluntarily recalled the product. These actions were due to the potential that ShapeMatch Cutting Guides may not have been manufactured in accordance with surgeon preoperative planning parameters or may have been manufactured outside of the planning ranges specified in the 510(k) clearance. This issue was identified through standard post-market surveillance of product complaints. A Product Notification was issued to surgeons and hospital risk managers which described the known hazards and harms potentially associated with the use of the affected products, which could result in a knee not functioning properly.

As stated in the January 2013 Product Notification, Stryker recommended that patient follow-up beyond the routine standard of care was not necessary.

Patients who have had knee replacement surgery in which ShapeMatch Cutting Guides were used and who feel their knee may not be functioning properly should contact their surgeon. Patients may also contact Stryker at 1-888-STRYKER with questions regarding this Class I recall Monday - Friday, 8am-8pm EST.

The ShapeMatch Cutting Guides have not been available on the market since November 2012. This voluntary recall does not affect the Triathlon Knee System or the Triathlon standard instrumentation.

Stryker is one of the world's leading medical technology companies and is dedicated to helping healthcare professionals perform their jobs more efficiently while enhancing patient care. The Company offers a diverse array of innovative medical technologies, including reconstructive, medical and surgical, and neurotechnology and spine products to help people lead more active and more satisfying lives. For more information about Stryker, please visit www.stryker.com.

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