Stryker Receives FDA 510(K) Clearance for Shapematch® Cutting Guides

May 24, 2011 7:59 AM ET

Kalamazoo, Michigan – May 24, 2011 - Stryker Orthopaedics, a division of Stryker Corporation (NYSE:SYK), today announced that its ShapeMatch Cutting Guides have been granted 510(k) market clearance by the U.S. Food and Drug Administration for use with the company's Triathlon Total Knee System. The single-use ShapeMatch Cutting Guides are designed and manufactured from patient-specific 3D imaging data that is derived from MRI or CT scans.

ShapeMatch Technology utilizes proprietary 3D imaging software to develop a customized pre-operative surgical plan for each patient. Upon surgeon review and approval, this plan is used to develop cutting guides for the individual patient. ShapeMatch Technology is only available for use with Stryker's Triathlon Knee System, which has demonstrated the best performance among the most frequently used brands of total knee implants as measured by revision rates in the National Joint Registry of England and Wales. (1,2)

Long-term demand for total knee surgery in the U.S. has been projected to continue increasing from 0.5 million procedures in 2005 to 3.48 million procedures in 2030.(3) The ability to contain costs and increase non-operative time efficiencies is important in meeting the demand for total knee surgery well into the future.

"We are excited to offer the Triathlon CustomFit Knee® with ShapeMatch Technology as a complement to our clinically successful Triathlon knee system," said Mike Mogul, Group President, Stryker Orthopaedics. "Achieving this clearance is an important milestone for the OtisMed business unit, and it demonstrates our commitment to bringing new, innovative technologies to market that have the potential to improve surgical and operating room efficiencies."

This technology has the potential to positively impact hospital costs associated with various stages of the patient care continuum during knee surgery. A study has shown that a reduction in instrumentation may provide a shorter procedural time(4) which may increase the potential capacity for additional procedures per day.(4,9)

About the Triathlon Knee
The Stryker Triathlon Knee System has been used in more than 750,000 procedures since its introduction in 2004 and is one of the fastest growing knee systems worldwide.(8) Studies have shown that Triathlon's single-radius technology is designed to allow for easier movement(6,7) and a study has shown a more rapid return to functional activities(5).

About Stryker
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.

Contacts

For media inquiries please contact:
Emily Peck, Kwittken & Company, 646-747-7149 or stryker@kwitco.com

For investor inquiries please contact:
Katherine A. Owen, Stryker Corporation, 269-385-2600 or katherine.owen@stryker.com

References:

1. The National Joint Registry of England and Wales Annual Report 2010. Table 3.11 Based on mean Revision Rates at three years according to brands for knee replacement procedures undertaken between 1st April 2003 and 31st December 2009, which were linked to a HES/PEDWepisode.

2. The National Joint Registry of England and Wales Annual Report 2009. Table 3.7 Based on mean Revision Rates at three years according to brands for knee replacement procedures undertaken between 1st April 2003 and 30th November 2008, which were linked to a HES/PEDWepisode.
3. Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am, 2007 Apr;89(4):780-5.
4. Stryker Orthopaedics – Precision Impact Assessment, Central Sterile Supply. March 21, 2008 (Presscott Associates Ltd.).
5. Harwin SF, Greene KA, Hitt K. Early experience with a new total knee implant: maximizing range of motion and function with gender-specific sizing. Surgical Technology International, 2007;16:199-205.
6. Ostermeier, S; Stukenborg-Colsman, C, Hannover Medical School (MHH) Hannover, Germany, "Quadriceps force after TKA - a comparison between single and multiple radius designs", Poster No. 2060. 56th Annual Meeting of the Orthopaedic Research Society.
7. Harwin SF, Greene KA, Hitt K. Triathlon total knee arthroplasty: 4-year outcomes with a high-performance implant. J Knee Surg. 2008 Oct;21(4):320-6.
8. Stryker Encompass Sales Reports: May, 2011.
9. Stahl JE, Sandberg WS, Daily B, Wiklund R, Egan MT, Goldman JM, Isaacson KB, Gazelle S, Rattner DW. Re-organizing patient care and workflow in the operating room: a cost-effectiveness study. Surgery. 2006 Jun;139(6):717-28.