ZIMMER BIOMET

Zimmer Prepared to Act on FDA Downclassification of Constrained Hips

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Availability will strengthen Zimmer position in growing hip revision market

WARSAW, Ind., May 24, 2002 /PRNewswire-FirstCall via COMTEX/ -- Leading orthopaedic manufacturer Zimmer says that it will file regulatory submissions to obtain clearance to market its constrained hip products and that inventory is in place to meet customer needs. The Food and Drug Administration (FDA) recently announced that it would downclassify constrained hip liners from Class III to Class II, effective May 30, 2002, potentially shortening the product review and approval cycle from years to months. "We will submit a 510(k) clearance request for the constrained version of our ZCA® All-Poly Acetabular Cup prior to the effective date, and one for our Trilogy® Acetabular System Constrained Liner within the next several days following the effective date," said Ray Elliott, Chairman, President and CEO of Zimmer Holdings, Inc. (NYSE: ZMH). "We are ready today to supply the market with these products -- they are on the shelf and ready to ship as soon as we receive clearance for our designs."

According to Zimmer, a key advantage of its constrained liner design is that it mates with existing shells from the Zimmer Trilogy Acetabular System, which is among the leading acetabular cup brands in the world. This allows surgeons to leave well-fixed acetabular shells in place during a revision surgery, and simply insert a new liner.

"The addition of these products will give Zimmer a complete line of acetabular options, from those for straightforward primary surgery, to constrained liners for dislocation problems, to roof rings and cages for the most complex reconstruction cases," said Dr. Kim Bertin, a Salt Lake City orthopaedic surgeon who participated in the design of Zimmer's Trilogy constrained liner.

Constrained liners are often used in revision surgeries to address situations where the hip has a tendency to dislocate. The extra constraint provided by the liner design helps keep the hip replacement components properly mated. The company said it is not aware of an estimate of the number of revision surgeries that would involve a constrained liner or cup, but industry sources estimate there are approximately 40,000 hip revisions performed in the U.S. each year. Growth in hip revisions is projected from 12 to 15 percent in coming years.

"We are looking forward to being able to add these products to our growing hip revision capability," said Elliott.

According to the FDA's guidelines, a Class II device is eligible for marketing clearance under the 510(k) process, where a manufacturer must demonstrate that a product is substantially equivalent to other previously approved and marketed devices. The Class III approval process involves clinical studies and typically takes several years from the time of application to marketing approval.

Zimmer constrained liners have been available in markets outside of the United States since last year.

Zimmer, based in Warsaw, Indiana, is a global leader in the design, development, manufacture and marketing of reconstructive orthopaedic implants and fracture management products. Orthopaedic reconstruction implants restore joint function lost due to disease or trauma in joints such as knees, hips, shoulders and elbows. Fracture management products are devices used primarily to reattach or stabilize damaged bone and tissue to support the body's natural healing process. Zimmer also manufactures and markets other products related to orthopaedic and general surgery. For the year 2001, Zimmer recorded worldwide revenues of approximately $1.2 billion. Zimmer was founded in 1927 and has more than 3,400 employees worldwide.

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