KneeAlign® 2 Receives FDA Market Clearance

Irvine, CA – April 7, 2011 – OrthAlign, Inc., a privately held medical device company, received 510(k) market clearance from the US Food and Drug Administration for the next generation KneeAlign® system, which now combines tibial and femoral knee replacement navigation in a single, disposable, palm-sized device. KneeAlign® 2 eliminates the need for an intramedullary rod by enabling the orthopedic surgeon to locate the center of the femoral head with a simple intraoperative maneuver.

Introduced in late 2010, KneeAlign® 1 has been widely endorsed by surgeons for its unique combination of precision and ease of use. In March 2011, the Journal of Arthroplasty published successful interim data of an ongoing KneeAlign® 1 clinical study. A total of 42 knees underwent a total knee replacement using KneeAlign® 1. Postoperative standing anteroposterior hip-to-ankle and lateral knee-to-ankle radiographs demonstrated that 97.6% of the tibial components were placed within 90° ± 2° to the mechanical axis in the coronal plane, and 96.2% of the components were placed within 3° ± 2° to the mechanical axis in the sagittal plane. KneeAlign® is compatible with all total knee replacement implant systems and offers the surgeon a clear and simple user interface within the operative field.

About OrthAlign, Inc.

OrthAlign is a privately held medical device company committed to providing orthopedic surgeons with user-friendly, cost-effective, surgical navigation products for precise alignment. We believe that our technology will raise the standard of care in Total Knee and Total Hip Arthroplasty surgeries by making consistent and measurable results accessible to all surgeons, hospitals, and patients. Our strategy is to leverage this technology to provide simple and precise alignment solutions for a broad range of orthopedic procedures. For more information regarding OrthAlign, please visit www.orthalign.com.

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