

Press release from Ortoma AB
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Ortoma obtains JP certification for hip implant planning module

Ortoma has obtained certification in Japan for its module OTS Hip Plan for pre-operative planning of hip replacement surgery. The marketing approval is an important step for launching OTS Hip, including modules for pre-operative planning and navigation of orthopedic hip implants, in Japan. The OTS platform is a surgical system that is assisted by AI (Artificial Intelligence) for improved accuracy, efficiency and surgical outcome.

Ortoma has a strategy to offer OTS Hip Plan for pre-operative planning in a stand-alone version as well as bundled with OTS Hip Guide for computer-assisted navigation. Therefore, separate regulatory applications for OTS Hip Plan and OTS Hip Guide are filed in Japan. The regulatory application for OTS Hip Plan has now been approved, and the stand-alone version of the product will be launched for clinical use in Japan. The JP regulatory application for OTS Hip Guide is pending examination. The bundle of OTS Hip plan and OTS Hip Guide will be launched in Japan when the regulatory application for OTS Hip Guide is approved.

“With the certification of OTS Hip Plan in Japan, we are ready to take the next step and introduce the product in Japan together with a strategic partner,” says Linus Byström, CEO of Ortoma.

In addition to the certification for marketing of OTS Hip Plan in Japan, the OTS platform includes CE marked products for hip replacement surgery and spine surgery. OTS for hip replacement surgery is also FDA 510(k) cleared for marketing in the USA. A FDA 510(k) application for OTS Spine Plan is pending in USA, and a regulatory application for OTS Hip Guide is pending in Japan.

Ortoma – Improved Performance

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About Ortoma AB (publ)

Ortoma AB develops surgical systems for the planning and positioning of implants in hip, knee and spinal surgery. The purpose of the company's surgical system, Ortoma Treatment Solution™ (OTS) is to enable the surgeon to accurately measure and plan 3D surgery for the placement of a joint implant and during the surgery, to optimally position the implant in the patient. Ortoma's surgical system is aimed at providing better patient outcomes, fewer complications and less follow-up surgeries - and thus better long-term survival rates for the implant. Another aim is to create a system that can be integrated easily into the processes and routines that are currently used in surgeries, thereby increasing efficiency. Ortoma's B shares are noted on Spotlight Stock Market. Globally, more than 7.5 million orthopedic procedures are performed each year where OTS could be used in hip, knee and spinal surgery. In Sweden last year around 42,000 surgical procedures were performed involving hip, knee or spinal surgery.