PRESS RELEASE Gothenburg 12th September 2017

Ortoma AB receives administrative acceptance review from FDA for Ortoma Treatment Solution™

FDA writes "An administrative acceptance review was conducted on your premarket notification (510(k)) K172515/S002, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review."

"- It is an extensive work with the FDA application that now enters its final phase. An approval from FDA opens the big American market for Ortoma, says CEO Matts Andersson."

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About Ortoma AB (publ)

Ortoma AB develops systems for planning and positioning of implants such as hip, knee and spine implants. Ortoma Treatment Solution™ (OTS) provides a 3D planning module for optimal positioning of the joint implant before surgery and a guide module that during surgery guides the surgeon in real time to the planned optimal position. OTS fits in to existing routines at the OR and there is no bulky hardware in the OP room. OTS aims to improve hospital efficiency and patient quality through decreased frequency of early post-operative dislocations and a possible better long term survival of the implant. Ortoma AB has more than 1.400 shareholders and is listed at Aktietorget.