

Möln dal 1 April 2020

FDA Approval of subcontractor for Axor II™

Integrum is glad to announce the approval of our prosthetic subcontractor by the FDA. The approval process was completed after a successful FDA inspection. This inspection included the PMA assessment in the scope.

This approval secures scalable deliveries to both the US and other markets and is an important milestone in the PMA application process.

The OPRA™ Axor™ II attaches to the Abutment end that is outside of the skin and acts as a safety connection between the Abutment and the prosthesis. It is designed to prevent damage to the bone-anchored Fixture and the skeleton. If overload occurs, the Axor™ II acts similar to a ski-binding and “releases” the prosthesis to protect the implant and the skeleton from damage.

Integrum is glad to continue providing the highest quality products that meets the requirements of safety for our patients.

The information in this press release is information that Integrum AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the contact person set out below, at 13:45 CET on April 1st, 2020.

Integrum AB is listed on Nasdaq First North in Stockholm. Erik Penser is the Company’s Certified Adviser.

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About Integrum

Integrum provides innovative solutions for bone-anchored prostheses. Integrum’s OPRA™ implant system improves quality of life for amputees through higher prosthetic functionality, improved comfort and improved mobility. With 20 years’ experience from more than 500 surgeries in 14 countries, Integrum is a global leader in bone anchored prostheses. The company’s share (INTEG B) is listed for trading on Nasdaq First North in Stockholm with Erik Penser Bank as Certified Advisor. Learn more at <http://integrum.se/>