2020-12-19

Mölndal, Sweden

Integrum AB granted PMA (premarket approval) by the FDA for the OPRA™ Implant System

Integrum is both extremely pleased, and proud, to announce the PMA approval issued by the Food and Drug Administration (FDA) in the US for the OPRA™ Implant System as a class III medical device.

In a release posted by FDA today, the agency stated:

"Today's approval of the OPRA Implant System expands options for prostheses for individuals who have had above-the-knee amputations and can help those who have had or may have problems with rehabilitation and have not been able to benefit from available socket prostheses," said Capt. Raquel Peat, Ph.D., MP.H., USPHS, director of the FDA's Center for Devices and Radiological Health's Office of Orthopedic Devices. "Prostheses can help people who have lost a leg due to trauma or cancer to regain mobility and to more easily participate in everyday activities."

Says Maria Lopez, CEO of Integrum "*We are thrilled by the FDA's decision and extremely proud of this unprecedented achievement by a Swedish Medtech company in dynamic growth*. *This approval further cements our position as global market leader in the bone-anchored; commonly known as the osseointegrated prosthesis market".*

The American Premarket Approval process is the most demanding regulatory process in the world. The approval marks the end of a process started in 2008, a process which required intensive work from the dedicated team within the company spearheaded by Professor Rickard Brånemark, Chairman of the Board, and Niklas Hovferberg, Head of Regulatory and Quality Affairs at Integrum. Over these many years, vast amounts of clinical and scientific data were compiled and analyzed, and, with the help and guidance of Hogan Lovells US LLP, the application; which consisted of several thousand pages, was completed and filed.

Due to the complex, rigorous, and resource-intensive nature of the PMA process, only a handful Swedish companies have been granted this approval. The approval well and truly cements Integrum's position as world leader within the field of bone-anchored prostheses.

Of equal significance is the fact that, in the very near future, the approval will make the dialogue with insurers much more straightforward, and vastly improve the likelihood of patients receiving reimbursement for the treatment from private insurers and public providers such as Medicare.

This disclosure contains information that Integrum AB is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on December 19th, 2020 at 00:30 CET. 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 AB is a publicly-traded company (INTEG B: Nasdaq First North exchange) based outside of Gothenburg, Sweden, with a US subsidiary in San Francisco, CA. Since 1990, osseointegration, the science behind the OPRA™ Implant System, has been helping individuals with amputations enjoy a dramatically improved quality of life. Thorough surgical experience gained over more than three decades, from 500 surgeries, in 14 countries, has led to the development of Integrum's system for bone-anchored prostheses – a vastly superior alternative to the traditionally used socket prosthesis.

The OPRA™ Implant System is the only FDA approved medical device for above-knee, bone-anchored prosthetics available in the US. More information on the company and its innovative solutions for amputees can be found at www.integrum.se.