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Biostock Studio: After receiving the PMA, Integrum looks to the future with confidence

In an interview with Biostock, Rickard Brånemark, founder and Chairman of the Board at Integrum AB, describes how receiving the PMA from the American FDA will have a very significant and positive impact on the future of Integrum.

The long and arduous process of obtaining a PMA for a class III medical device is an amazing milestone that only a handful Swedish medical device companies has achieved. The investment of 19 years and countless resources in manpower, funds, and clinical research activities, is well worth it, as the effects are becoming more and more apparent.

Not only does the PMA approval lead to a virtual monopoly situation for the OPRA™ Implant System on the largest market in the world for at least the next 3 years, there are further positive and tangible implications as well.

The approval also brings with it a “quality stamp” which makes both patients and clinicians regard the treatment as a “standard of care”, rather than a form of research-oriented treatment, which makes patient recruitment easier. This places Integrum in a position of strength in the dialogue with public and private insurers, who will become more likley to offer funding for patients in need. The PMA will also pave the way for a standardized reimbursement structure, albeit several years out.

Outside of the US, the PMA will effectively “raise the eyebrows” of clinicians and regulatory bodies alike, accelerating expansion in markets where the OPRA™ Implant System is already present. Moreover, the approval will facilitate entry into new key strategic markets such as China and Japan, and, as in the US, make it easier for clinical professionals to recommend the treatment for patients who needlessly suffer the ill side-effects of the current “standard of care”; which is socket prostheses.

To watch the full interview (in Swedish) click here.

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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 prostheses available in the US, and the only such device in the world to have received a PMA from the FDA for this treatment indication. More information on the company and its innovative solutions for amputees can be found at www.integrum.se.