



Episurf Medical: Approaching 510(k) submission for big toe implant

Episurf Medical (NASDAQ: EPIS B) today provides an update on the planned 510(k) filing to the US FDA for the company's implant for the 1st MTP joint of the big toe. The company plans to file the 510(k) submission for US market clearance during the coming weeks. The company aims to receive clearance to be able to launch the product on the US market during 2024. The company is currently assessing various options for commercialization strategy, including independent distributors and technology licensing.

The implant is intended to treat osteoarthritis (hallux rigidus) in the big toe. It is based on Episurf Medical's proprietary technology for patient-specific design of implants and surgical instruments. Post-clearance, the product will expand the company's total addressable market by approximately \$400 million while adding over 10,000 surgeons to the company's target customer list.

"Initial test results have all been favorable, and the implant is currently undergoing further bench testing to support the filing. The US market is our most important commercial opportunity, and together with the FDA-cleared Episealer® Patellofemoral System, we aim at further establishing our market presence in the US during the rest of 2023 and 2024," says Pål Ryfors, CEO Episurf Medical.

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About Episurf Medical

Episurf Medical is endeavoring to bring people with painful joint injuries a more active, healthier life through the availability of minimally invasive and individualised treatment alternatives. Episurf Medical's Episealer® individualised implants and Epiguide® surgical drill guides are developed for treating localised cartilage injury in joints. Episurf Medical's µiFidelity® system enables implants to be cost-efficiently tailored to each individual's unique injury for the optimal fit and minimal intervention. Episurf Medical's head office is in Stockholm, Sweden. Its share (EPIS B) is listed on Nasdaq Stockholm. For more information, go to the company's website: www.episurf.com.

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