



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

Episurf Medical (NASDAQ: EPIS B) today announces that a 510(k) filing to the US FDA for market clearance of the company's toe implant for the 1<sup>st</sup> MTP joint is being submitted today. The submission will now undergo a review process and the company aims to receive clearance to be able to launch the product on the US market during 2024.

*"This is a significant milestone which we have been looking forward to for quite some time. With this product, we are entering into a fast-moving and fast-growing market segment, with a totally unique solution. This is also the last piece of the puzzle of our current strategy, and with the launch of this product, we will have expanded our product offering in line with our plans to accelerate our commercial strategy. We are very pleased to have reached this milestone, and we look forward to a constructive dialogue with the FDA",* says Pål Ryfors, CEO, Episurf Medical.

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, a disease affecting several million Americans each year. It is based on Episurf Medical's proprietary technology for patient-specific design of implants and surgical instruments. The product is estimated to expand the company's total addressable market by approximately \$400 million while adding over 10,000 surgeons to the company's target customer list.

## **For more information, please contact:**

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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 µFidelity® 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](http://www.episurf.com).*

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