Company Announcement
April 18, 2016

Episurf Medical will pursue the FDA pre-submission and 510(K) regulatory pathway for US market entry

Episurf Medical has received the recommendation from Experien Group to follow a FDA pre-submission and 510(K) regulatory pathway for a US market entry

In preparation for a US market entry, Episurf Medical appointed California based Experien Group to help define the most appropriate regulatory strategy for a Food and Drug Administration (FDA) submission process. Following a comprehensive analysis, Experien Group highly recommends that Episurf Medical engages with the FDA through a Pre–Submission meeting to discuss the technology, proposed indications for use, and proposed performance testing with the FDA prior to submission of a Premarket notification 510(k).

'Episurf Medical's intention is to enter the US market, which is the world's largest orthopaedic market. We are delighted that Experien Group recommends the 510(k) route, which we believe is the most expedient way to reach the US market', says Rosemary Cunningham Thomas, CEO, Episurf Medical.

Episurf Medical will have the opportunity to obtain FDA feedback on the proposed 510(k) strategy to secure a solid regulatory pathway for the product portfolio. Episurf Medical will further become familiar with the FDA reviewers and their expectations. Although decisions made at a FDA meeting are non-binding, the meeting provides an opportunity for FDA to become familiar with the technology which is a benefit when the 510(k) is filed.

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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 personalized treatment alternatives. Episurf Medical's Episealer® personalized implants and Epiguide® surgical drill guides are developed for treating localized 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. The information in this press release is such that Episurf Medical AB is required to disclose in accordance with the Securities Markets Act and/or the Financial Instruments Trading Act.