

Episurf Medical continues its communication with the US Food and Drug Administration (FDA) regarding appropriate route for market acceptance in the US

In July 2016, Episurf Medical participated in a pre-submission meeting with the FDA in Washington. Following this meeting, Episurf Medical submitted a 513(g) Request for Information for obtaining FDA's views about the classification and the regulatory requirements that may be applicable to the Episealer device.

Episurf Medical has now received feedback from the FDA regarding the 513(g) request. The feedback is not decisive and opens up various alternatives for Episurf Medical to assess; further interaction with the FDA has been initiated. There are several factors to consider when deciding what regulatory pathway to select and what kind of application to submit to the FDA. Episurf Medical has started an internal process to decide on a regulatory pathway for application for US market acceptance. The Company expects to complete its review and reach a decision by the third quarter of 2017.

"With our European launch of the Episealer technology now well underway, we are eager to move on with the strategic development and regulatory process for the important North American market. We are happy to now have feedback on our 513(g) application, and we look forward to continuing our constructive interaction with FDA in determining our best route forward." comments Pål Ryfors, Acting CEO and CFO, 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 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 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.

This information is information that Episurf Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 14.45 CET on 15 May 2017.

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