

Amplitude Surgical files for American FDA 510(k) approval for its posterior-stabilized knee prosthesis ANATOMIC

Valence, June 9, 2016 – Amplitude Surgical (ISIN: FR0012789667, Ticker: AMPLI, PEA-PME eligible), a leading French player on the global surgical technology market for lower-limb orthopedics, announces that it has filed for 510(k) approval with the U.S. Food and Drug Administration (FDA) for its posterior-stabilized knee prosthesis ANATOMIC.

Olivier Jallabert, Chairman and CEO of Amplitude Surgical, says: *“The penetration of the American market, the world’s largest market for lower limbs prosthetic reconstruction, is a major strategic pillar for our future development. Therefore, a few months after the approval of our Novastep product range for extremities surgery (foot and ankle), we have just filed for marketing clearance for our ANATOMIC knee prosthesis product range.”*

The ANATOMIC[®] fixed bearing knee prosthesis illustrates the capacity of innovation and the attention that Amplitude Surgical pays to the needs expressed by surgeons. After a registration in Europe in February 2013, in Australia in August 2015 and more recently in South Africa, it is now in the United-States that the Group files for 510(k) approval. Since its launching, the posterior-stabilized knee prosthesis ANATOMIC product range meets great success with more than 17,000 performed surgeries and it already reaches the highest sales of the company.

In the United States, the world’s largest market for lower limbs prosthetic reconstruction, €8bn and almost 50% of the worldwide market, this filing is a continuation of FDA’s marketing clearance of the Novastep product range for extremities surgery (foot and ankle).

Next financial press release: 2015-16 annual sales, on Wednesday July 20, 2016, after market.

About Amplitude Surgical

Founded in 1997 in Valence, France, Amplitude Surgical is a leading French player on the global surgical technology market for lower-limb orthopedics. Amplitude Surgical develops and markets high-end products for orthopedic surgery covering the main disorders affecting the hip, knee and extremities, and notably foot and ankle surgery. Amplitude Surgical develops, in close collaboration with surgeons, numerous high value-added innovations in order to best meet the needs of patients, surgeons and healthcare facilities. A leading player in France, Amplitude Surgical is developing abroad through its subsidiaries and a network of exclusive distributors and agents. Amplitude Surgical operates on the lower-limb market through the intermediary of its Novastep subsidiaries in France and the United States. Amplitude Surgical distributes its products in more than 30 countries. On June 30, 2015, Amplitude Surgical had a workforce of 248 staff and recorded sales of 71.1 million euros and an EBITDA margin of close to 19%.

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