



Materialise Receives FDA NSE Letter for X-Ray 510(k) Submission

December 22, 2015

LEUVEN, Belgium--(BUSINESS WIRE)--Dec. 22, 2015-- [Materialise NV](#) (Nasdaq: MTLN), announced today that the company is in receipt of a not substantially equivalent (NSE) letter from the U.S. Food and Drug Administration (FDA) regarding the 510(k) submission for its innovative X-ray knee guide system. The system is intended to be used as a surgical instrument to assist in the positioning of total knee replacement components, without MRI or CT.

Materialise NV offers health care professionals a full range of 3D surgical planning solutions, including personalized knee replacement solutions based on CT or MRI images, which are cleared by the FDA.

Wilfried Vancaen, Founder and CEO of Materialise states, "We are disappointed that the FDA concluded that, based on the information submitted, our X-ray knee guide system cannot be considered as substantially equivalent to our solutions based on CT or MRI images. While this decision will impact the timing of the marketing of our innovative solution in the United States, we will continue to pursue the regulatory clearance process, taking into account the feedback from the FDA."

Cautionary Statement on Forward-Looking Statements

Some of the statements in this press release are "forward-looking" and are made pursuant to the safe harbor provision of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include statements relating to, among other things, our planned commercialization efforts and regulatory approvals of our technologies as well as the success thereof and our research and development projects. These forward-looking statements are based upon the expectations of management under current assumptions at the time of this press release. We caution you that forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control that may cause our actual results to differ materially from our expectations. We are providing this information as of the date of this press release and do not undertake any obligation to update any forward-looking statements contained in this presentation as a result of new information, future events or otherwise, unless we have obligations under the federal securities laws to update and disclose material developments related to previously disclosed information.

About Materialise

With its headquarters in Leuven, Belgium, and branches worldwide, Materialise is a provider of Additive Manufacturing (AM) software solutions and sophisticated 3D printing services in a wide variety of industries, including healthcare, automotive, aerospace, art and design and consumer products. Materialise has been playing an active role in the field of AM since 1990, through its involvement in AM for industrial and medical applications, by providing biomedical and clinical solutions such as medical image processing and surgical simulations and by developing unique solutions for its customers' prototyping, production, and medical needs. For additional information, please visit: www.materialise.com.



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