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ASIA EDITION

Korean firm Lunit set to launch 3D Breast Tomosynthesis AI solution in European market

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Lunit seeks FDA clearance, paving the way into the US market

South Korea-based Lunit, a leading global provider of artificial intelligence (AI)-powered cancer solutions, has announced that its AI solution for 3D Breast Tomosynthesis (DBT) analysis, Lunit INSIGHT DBT, has met the requirements of the CE marking under Europe's latest Medical Device Regulation (MDR).

The MDR CE certification is a more stringent requirement for medical devices than the existing Medical Device Directive (MDD), ensuring higher performance and quality standards. From May 2024, products without MDR CE certification will be banned from sale in the EU, making it vital for companies to obtain this certification to enter the market.

In 2022, Lunit secured CE marking under EU MDR for Lunit INSIGHT CXR, an AI solution for chest x-ray analysis, and Lunit INSIGHT MMG, an AI solution for mammography analysis, becoming the first software as a medical device (SaMD) company in the Asia Pacific region to earn it.

Lunit developed Lunit INSIGHT DBT based on the evaluation that Lunit INSIGHT MMG is one of the most precise AI for commercialised breast screening. Lunit INSIGHT DBT analyses 3D images from DBT to enable fast and accurate diagnosis of breast cancer. Lunit plans to commence the launch of Lunit INSIGHT DBT in the European market with a planned start date around the end of March.

Within the third quarter of this year, Lunit intends to start the process of obtaining FDA approval for Lunit INSIGHT DBT as a means to enter the US market.