Therapixel receives FDA 510(k) clearance for MammoScreen^{TM}

AI-powered reading aid for screening mammography improves Radiologists' performance in cancer detection

PARIS July 9, 2020 – MammoScreen^{TM}, the explainable and actionable artificial intelligence (AI) based software assisting Radiologists in reading screening mammograms, received 510(k) clearance K192854 from the U.S. Food and Drug Administration (FDA).
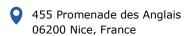
This FDA clearance was received after submitting results from a multi-reader multi-case study conducted last year. Study findings revealed improvement in readers' performance in cancer detection in mammograms when paired with MammoScreen compared to radiologists alone.

"Receiving FDA clearance for MammoScreen is a major milestone for Therapixel," said Pierre Fillard, Founder and Chief Scientific Officer of Paris-based Therapixel. "This is the result of our collaboration with radiologists over the last three years to turn the algorithm that won the DREAM challenge in 2017 into a powerful product that is truly meaningful to their day-to-day-work."
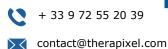
MammoScreen automatically detects and characterizes suspicious soft tissue lesions and calcifications in mammogram images while assessing their likelihood of malignancy. The results are presented in a summary report that characterized suspiciousness of each lesion scored on a scale of 1-10, with 1, being least likely to reveal malignancy and 10 most likely.

"We believe MammoScreen will provide quick and reliable confirmation of Radiologists' suspicions as they read," said Matthieu Leclerc-Chalvet, Therapixel CEO. "This AI solution will ensure a more certain assessment by Radiologists and a speedier reassurance of women having breast cancer screening exams, resulting in a more efficient workflow and reduced costs for the healthcare system. We look forward to installing MammoScreen in radiology departments and institutions across the U.S. so imaging professionals and women can benefit from its use."

Breast cancer is the second cause of cancer death worldwide. In the United-States, 1 in 8 women will develop breast cancer during their lifetime. Early detection is the key to successful treatment.

About Therapixel

Therapixel is a French company specialized in the design and commercialization of AI-powered medical imaging software, with the goal of delivering pertinent information at the right time to healthcare professionals. Winner of the Digital Mammography DREAM Challenge in 2017, the global competition on breast cancer detection with AI, Therapixel has developed MammoScreen™, a software that helps with the interpretation of screening mammograms. With MammoScreen™, even experienced radiologists can improve their performance, feel more confident in their judgment and reassure women quicker. Find more at www.mammoscreen.com

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