

This article was originally published [here](#)



Medical imaging tech developer [Subtle Medical](#) said today that it won both CE Mark approval in the European Union and FDA 510(k) clearance for its SubtlePET artificial-intelligence-powered positron emission topography imaging enhancement system.

The SubtlePET system is designed to enhance images and reduce scanning times to improve overall patient experience during imaging procedures, the Menlo Park, Calif.-based company said.

“Focusing Subtle Medical’s SubtlePET AI platform on faster image acquisition, we have been able to dramatically increase PET scan efficiency and provide a superior patient experience. SubtlePET technology allows us to scan a patient four times faster than normal, yet maintain equal image quality, not otherwise impacting work flow. This creates immediate ROI benefit for our hospital and a compelling value proposition. I’m looking forward to seeing more groundbreaking technology from the Subtle team,” Dr. Michael Brant-Zawadzki of Newport Beach, Calif.-based Hoag Hospital said in a prepared statement.

Subtle Medical said that the system is currently in pilot clinical use in multiple university hospitals and imaging centers in the US and internationally, the company said.

The company added that it is developing additional products it will seek FDA clearance for, including the SubtleMR for MRI scanning uses and the SubtleGAD for gadolinium dosage during imaging procedures.

“This FDA clearance is a key milestone in Subtle Medical’s mission to bring novel and empathetic deep learning to improve patient satisfaction. The accomplishment of having the first AI cleared for use in nuclear medicine applications validates our team’s strength and the commitment of our collaborators. Our focus on image acquisition and workflow differentiates us from other AI companies that are working on post-processing and computer-aided diagnosis products. We are not replacing radiologists—we are addressing the tremendous cost to U.S. healthcare by leveraging deep learning in imaging at the infrastructure level to enable better and higher quality care,” founder & CEO Enhao Gong said in a press release.

## Subtle Medical wins FDA nod, CE Mark for SubtlePet AI-powered imaging system

The post [Subtle Medical wins FDA nod, CE Mark for SubtlePet AI-powered imaging system](#) appeared first on [MassDevice](#).