

## Koios Medical Announces CE Mark Approval and European Market Launch for Breast Cancer Detection Al Software.

Koios Medical, a fast-growing developer of Al-based software received CE Mark approval for its system to accurately diagnose breast cancer via ultrasound.



NEW YORK, NY, USA, March 16, 2021 /EINPresswire.com/ -- Koios Medical,

Inc., a fast-growing developer of artificial intelligence software for physicians announced it has received Conformité Européenne (CE) Mark approval for its flagship Koios DS Breast decision support software for interpreting breast ultrasound images. Available commercially in the US since 2018, physicians using the software consistently find cancer detection rates increase while simultaneously reducing all too common and costly false positive, benign biopsy rates, effectively elevating the accuracy of diagnosis and the quality of care provided to patients.

Initially cleared for use by the USFDA in late 2016 with an upgraded version also cleared in mid-2019, Koios DS AI software is deployed at a rapidly growing number of hospital systems, clinics and academic medical centers in the US, the Middle East and South America. CE Marking now makes this innovative software commercially available in another 38 countries across Europe and beyond. One out of every eight women is expected to contract breast cancer over the course of her lifetime making breast cancer the leading cancer diagnosis in women worldwide. The earliest possible detection is critical to increased survival rates. The use of AI software can dramatically expand access to quality care, improve accuracy, early diagnosis and survival.

Koios DS Breast Smart Ultrasound AI software was trained on over 500,000 ultrasound images of both malignant and benign breast lesions to improve physician diagnostic accuracy. The system generates a likelihood of malignancy finding aligned to both the American College of Radiology's BI-RADS rating schema and the European five-point rating systems to both streamline workflow and ensure a proper treatment pathway.

Despite the advances of mammography technology, ultrasound remains the standard of care modality for nearly half the women around the world that have dense breast tissue. Both cancer and dense breast tissue appear indistinguishable from one another on a mammogram making ultrasound the recommended and preferred imaging modality to accurately diagnose

abnormalities found during routine screening. Using AI to analyze ultrasound images holds the promise of reducing breast cancer mortality worldwide with improved diagnostic accuracy while also eliminating avoidable benign biopsies.

"We could not be more pleased to introduce our innovative AI software for breast ultrasound exam interpretation to physicians in the UK, EU, Turkey and beyond." Says Dr. Lev Barinov, VP of Clinical Excellence. "Use of Koios DS Breast can consistently elevate the performance of any trained physician interpreting breast ultrasound to the level of accuracy of a world class breast expert."

Koios DS Breast software is used in conjunction with all major PACS platforms and is directly available on the LOGIQTM E10, GE Healthcare's next generation digital ultrasound system that integrates artificial intelligence, cloud connectivity, and advanced algorithms to acquire and reconstruct data. Machine generated results can be exported directly into a patient's medical record. Koios Medical is currently preparing a version for thyroid ultrasound image data analysis and expects to add thyroid capabilities to its offering later this year.

"Koios DS Breast will bring a proven solution to the international healthcare marketplace for improved diagnostic accuracy combined with speed physicians expect that is certain to improve patient care, control costs and, most importantly, save lives. Many of the physicians and institutions soon to become our new partners have the proper incentives in place to accelerate adoption with their focus on value and quality. We share that same commitment and look forward to celebrating the results we have seen in the US with physicians and patients across Europe," says Koios Medical CEO Chad McClennan, MBA.

## **About Koios Medical:**

Koios Medical develops medical software to assist physicians interpreting ultrasound images and applies deep learning methods to the process of reaching an accurate diagnosis. The Koios DS platform uses advanced AI algorithms to assist in the early detection of disease while reducing recommendations for biopsy of benign tissue. Patented technology saves physicians time, helps improve patient outcomes, and reduces healthcare costs. Koios DS (decision support) is presently focused on the breast and thyroid cancer diagnosis markets. Women with dense breast tissue (over 40% in the US) often require an alternative to mammography for diagnosis. Ultrasound is a widely available and effective alternative to mammography using no ionizing radiation and is a standard of care for breast cancer diagnosis. To learn more please contact us at info@koiosmedical.com or (732) 529-5755.

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