Koios Medical Announces CE Marking for Smart Ultrasound® Software for Thyroid and Breast Cancer Diagnosis

Radiology AI software for early cancer diagnosis uses computer vision to automate interpretation and reporting now available across EU and UK.

NEW YORK, NY, UNITED STATES, December 5, 2022 /EINPresswire.com/ -- Koios Medical, a leader in cancer diagnosis using ultrasound, announced receiving CE Marking under the EU MDR for Koios DS, an artificial intelligence (AI) based software platform proven to accurately diagnose both thyroid and breast cancers in ultrasound exams. The novel, dual-diagnosis system, built using data sourced from a global network of 55 sites, aids physicians in quickly and accurately diagnosing disease, improves speed of interpretation, automates reporting, and reduces time to treatment while avoiding unnecessary surgical procedures.

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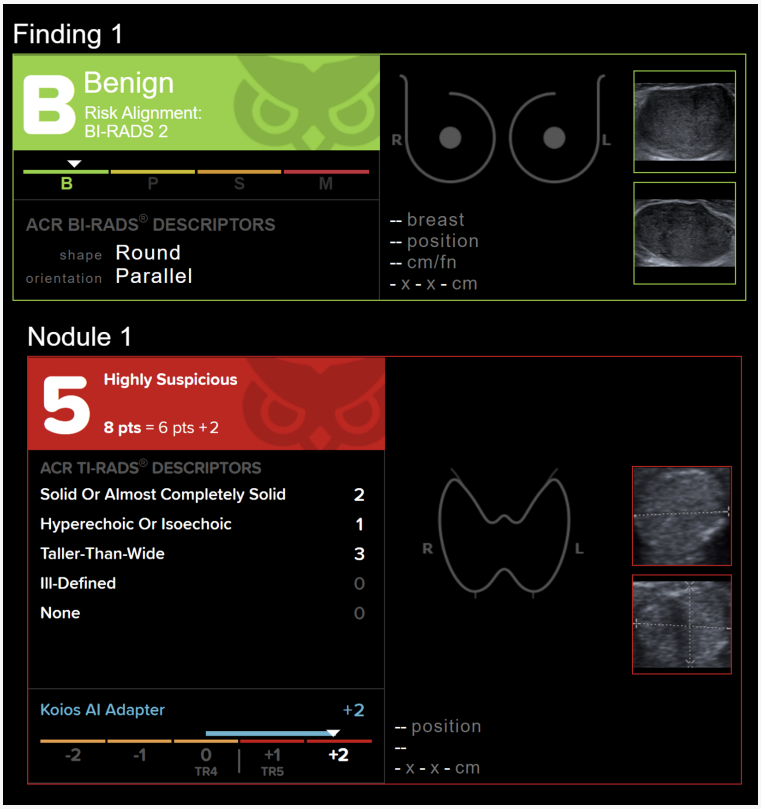
> *Dr. Shah Islam, National Hospital for Neurology & Neurosurgery, London.*

"Koios DS for breast and now thyroid ultrasound exam interpretation and automated reporting is a game changer. Not only will it aid diagnosis of both thyroid and breast cancer, it will allow for more standardized reporting of thyroid nodules preventing potentially unwarranted biopsies on benign lesions and earlier detection and diagnosis," says Dr. Shah Islam, National Hospital for Neurology & Neurosurgery, London.

The world is facing a significant and growing shortage of radiologists creating an environment that demands innovative solutions that will improve efficiency and reduce time consuming tasks, errors and procedures.

Ultrasound technology is standard of care for both breast cancer and thyroid disease diagnosis. Thyroid exams are one of the most complex, challenging interpretations for radiologists. Diagnostic uncertainty drives a high level of variability across physicians and results in large volumes of surgical procedures, downstream costs, risks of complication, and physician burn-out.

Clinical studies showed thyroid cancer detection rates jumped by up to 14% when physicians utilize Koios DS software while simultaneously reducing false positive biopsy orders by over 35%. Interpretation time per case dropped by over 24% while variability was lowered by over 50%.



Automated Findings Report

FDA Cleared for use and in the US since late 2021 and with CPT® Category III billing codes available since early 2022, the billable, multiple indication medical device software is now available across the EU and UK. In the US alone, breast and thyroid cancers combine for over 375,000 diagnosed cases annually. Over 2.2 million biopsy procedures of breast and thyroid tissue are performed yearly, yet tens of thousands of cancers still go undetected.

“The typical clinical decision-making paradigm relies on tradeoffs; trading sensitivity for specificity, efficiency for thoroughness, but the only thing enforcing this paradigm is the inability to shift off these tradeoff curves in place of shifting along them. This novel software demonstrates when using AI for decision support, physicians experience clinically meaningful shifts in performance, improving interpretation efficacy and diagnostic performance, improving sensitivity and reducing false positives. It is exciting to bring these innovations to physicians and ultimately their patients to elevate care globally,” says Dr. Lev Barinov, Clinical and R&D Advisor.

Koios DS patented software aligns AI generated findings directly to the Royal College of Radiology U1-U5 and ACR TI-RADS rating systems for tissue classification, scoring, and patient management.

“The ability of physicians and health systems to now code and bill for the use of this innovative and effective technology will most certainly accelerate adoption, putting the software into the hands of physicians for the benefit of patients nationwide,” says Graham Anderson, Koios Medical CFO.

The CE Marking process required that Koios DS be proven to accurately interpret images from all major ultrasound hardware manufacturers. The software is compatible with any PACS workstation viewer and integrated into GE Healthcare's LOGIQ, Fortis and ABUS ultrasound scanners. The system enables real-time decision-making with results exportable directly into a patient's record and all major reporting systems, reducing errors and saving time.

"The loss of life to cancers missed, found too late or misdiagnosed is tragic. When combined with the millions wasted on avoidable procedures we are compelled to relentlessly innovate, building powerful AI models directly into easy-to-use software. CE Marking under the new EU MDR for Koios DS means physicians are now poised to save tens of thousands of lives while freeing up precious time and resources that can be used more effectively elsewhere while elevating quality of life," says Koios Medical CEO Chad McClennan.

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