

Toku Obtains CE and UKCA Marks for Al Cardiovascular Risk Assessments Through the Eye



Toku's patented AI technology, CLAiR, has obtained CE and UKCA Marks. CLAiR provides fast, accurate, non-invasive cardiovascular disease (CVD) risk assessments using standard retinal images. By enabling assessment at the point of care, CLAiR will make detection of CVD risk more accessible, especially for underserved populations who lack healthcare access. By integrating seamlessly with existing retinal cameras, CLAiR enables widespread access to CVD assessments through eye care clinics, primary care, and pharmacies. This improved access can lead to earlier detection - saving lives and reducing healthcare costs.

Toku, Inc., a commercial medical device company specializing in AI assessment of retinal images, announced that it has obtained CE and UKCA Marks for its patented CLAiR technology. This significant milestone underscores Toku's commitment to maintaining the highest standards of quality and safety and allows access to the Europe and United Kingdom markets.

CLAiR provides accurate, affordable, non-invasive evaluation for the risk of cardiovascular disease (CVD) at the point of care using retinal images captured during a routine eye exam.

The retina, located in the back of the eye, is the only part of the vascular system that can be photographed easily and non-invasively. The CLAiR technology integrates readily with existing retinal cameras, to provide real-time CVD risk assessments with accuracy comparable to gold standard cardiovascular risk assessments (which typically require blood tests and can take weeks). The Al-powered CLAiR technology identifies elevated cardiovascular risk by analyzing minute changes in the retina and its vasculature. CLAiR results can be shared with a patient's primary care physician, who can initiate a comprehensive cardiovascular evaluation to guide prevention.

Retinal imaging is routinely performed in many eye care settings and is increasingly being used in pharmacy and primary care clinics across the UK and EU. CLAiR will enable healthcare providers in various settings to identify elevated cardiovascular risk in adult patients with no known history of cardiovascular disease.

"I believe that a retinal image can be considered the 'fifth vital' along with temperature, heart rate, respiration rate, and blood pressure," says Toku CEO Associate Professor Ehsan Vaghefi. "The CE and UKCA marks allow us to bring CLAiR to patients across multiple geographies. In my vision of the future, a retinal image analysis is an integral part of a comprehensive screening for major diseases such as cardiovascular or kidney disease."

Professor John Marshall, the holder of the original patents for refractive surgery and Emeritus Professor of Ophthalmology at both University College London & Kings College, London says "The eye is the only organ of the body where we can non-invasively view and image blood vessels. The advent of artificial intelligence has enabled analysis of retinal images to predict the occurrence and time course of numerous diseases of the vascular system, including heart attacks and strokes. Such early risk identification allows timely modification of lifestyle and even earlier treatment to prevent or delay onset. Toku's CLAiR algorithm is a major breakthrough in the field of cardiovascular diseases and should result in lifesaving interventions and improved quality of life for innumerable individuals throughout the world."

Source & Image Credit: Business Wire

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