Frontier X Plus Secures FDA 510(k) Clearance, Setting New Standards in Heart Health

Frontier X Plus Expands into U.S. Market with Independent Diagnostic Testing Facilities Partnerships and Plans for AI-Enhanced Heart Monitoring


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NEW YORK, NY, UNITED STATES, November 14, 2024 / EINPresswire.com/ -- Fourth Frontier, a medical technology company based out of New York and Bangalore, announced the 510(k) clearance of the Frontier X Plus from the U.S. FDA. The Frontier X Plus is an innovative single-lead, continuous ECG monitor that is worn around the chest and wirelessly relays the user's ECG instantly to remote dashboards. A range of advanced algorithms identify and classify cardiac rhythm as Bradycardia, Tachycardia, Normal Sinus Rhythm, or Atrial Fibrillation. The device demonstrated best-in-class signal quality during a range of motions including during intense exercise. The wearable ECG monitor further demonstrated equivalence in the classification of cardiac arrhythmias when compared with the conventional 12-lead ECG, through clinical trials in India and the US.

According to the Center for Disease Control, one person dies every 33 seconds from Cardiovascular Disease (CVD), and CVDs are responsible for one in every five deaths in the US. The American Heart Association reports that between three to six million Americans have reported an incidence of Atrial Fibrillation. This number is expected to rise to 16 million by 2050. Atrial Fibrillation has been described as a global epidemic and is a key indicator of reduced morbidity and mortality in individuals of all age groups. Globally, the incidence and prevalence of Cardiovascular Disease (CVD) has been increasingly observed in younger individuals and is one of the leading reasons for premature death.

"We have seen cardiac arrhythmias develop in individuals of all ages, and the incidence is significantly higher for individuals who are both active and have cardiac health risk factors. The percentage of population that falls in the confluence of these categories is continuously rising. Since the FX+ is able to capture ECGs during all kinds of motion and activity, we think this will be

a game changer and significantly improve the early detection of cardiovascular disease", said Manav Bhushan, co-founder and CEO of Fourth Frontier.

With this clearance, the company plans to enter the US market as a prescription based, class II medical device. Fourth Frontier will partner with Independent Diagnostic Testing Facilities (IDTFs) and cardiac rehabilitation centers to offer at-home remote monitoring services. In the near future, the company has plans to introduce AI algorithms which analyse the ECG for early diagnosis of different kinds of heart conditions, a potential breakthrough for people using the device in their everyday lives.

About Fourth Frontier:
Fourth Frontier is a pioneering health tech company that builds and offers products and services for monitoring and improving heart health for people across the world. Cardiovascular disease is the leading cause of mortality across the globe. Despite its importance, affordable products and services to monitor and improve heart health from the comfort of the home have not been available to consumers. Fourth Frontier is committed to solving this important problem.
With over 150 million minutes of data, 120,000+ users, and a presence in 4,000+ cities across 50+ countries, the device is trusted by people who want to enhance their heart health and fitness.

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