

Nuubo Receives U.S. FDA 510(k) Clearance for the Nuubo System

MADRID, August 16 - Spanish medical device innovator Nuubo (<https://www.nuubo.com>) today announced it has received United States Food and Drug Administration (FDA) 510(k) clearance to market its Nuubo System, a disruptive wireless, textile-based ambulatory electrocardiogram (aECG) technology that enables mid and long-term monitoring for cardiac arrhythmia diagnosis.

The Nuubo System is designed to obtain the highest ECG signal quality while achieving best-in-class patient comfort for monitoring up to 30 days. The non-invasive device consists of a seamless wearable fabric with multi-lead sensor technology that is flexible and stretchable. The Nuubo System is simple to use and has no adhesives or wires, improving patient comfort while increasing patient compliance and arrhythmia diagnostic yield.

The FDA clearance allows Nuubo to market and sell the Nuubo System to US hospitals and clinics for use in detecting and monitoring cardiac arrhythmias for ambulatory patients. The Nuubo System will be prescribed by a qualified healthcare professional when diagnostic and post-procedure monitoring is needed. The company anticipates US commercial availability of the Nuubo System later this year.

"We are pleased to have received FDA 510(k) clearance to bring the Nuubo System to US healthcare providers and patients," said Juan Alcántara, Nuubo CEO. "With more than 25,000 patients monitored by Nuubo in Europe, we are ready to launch in the US, the largest aECG market."

Alcántara also noted that Nuubo system is the fifth Spanish FDA cleared product in the past five years. "This great accomplishment is the result of hard work from Nuubo's talented team and their commitment to patient-centric ECG technology innovation. In addition to recognizing the Nuubo team for this achievement, I also want to thank the Nuubo board members and investors for their continued support," said Alcántara.

"This is just the beginning of an exciting journey to provide cardiologists and patients with a better aECG monitoring experience," said Daniel Llorca, Nuubo Product Development Director. "Nuubo is committed to better patient outcomes and innovation in digital remote aECG technologies. We are excited about the US launch of the Nuubo System and look forward to the future of Nuubo and its near-term product pipeline."

About Nuubo:

Nuubo is a venture capital backed medical device company headquartered in Madrid, Spain, focused on aECG technologies for cardiac disease prevention, diagnosis and rehabilitation. Nuubo's wireless, wearable textile electrode devices are designed to obtain the best ECG signal while achieving best-in-class patient comfort for mid and long-term aECG monitoring. In Europe, the company has monitored over 25,000 patients to date with the technology. While the 510(k) clearance indication is specifically for arrhythmia diagnosis, in Europe the company also serves the cardiac rehabilitation and chronic cardiac condition ECG monitoring markets.

For more information, please visit <https://www.nuubo.com>.

Media Contact:

Smart Solutions Technologies S.L., doing business as Nuubo

Email: info@nuubo.com

Phone: (+34) 91 360 44 31