

## **Aktiia's Hilo Band Becomes First Cuffless Blood Pressure Monitor Cleared by FDA for Over-the-Counter Use**

*The FDA-cleared G0 Blood Pressure Monitoring System - marketed as Hilo Band - will bring cuffless blood pressure monitoring to U.S. consumers*



[www.hilo.com](http://www.hilo.com)

**Neuchâtel, Switzerland – July 9, 2025** – Aktiia, a pioneer in optical blood pressure monitoring, announced today that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for over-the-counter (OTC) use of its cuffless blood pressure monitoring technology. This clearance, granted for Aktiia's G0 Blood Pressure Monitoring System, marks the first time the FDA has cleared a cuffless blood pressure monitor indicated for over-the-counter (OTC) use in the United States. While Aktiia's innovative blood pressure monitoring products are already CE marked and available in Europe under the brand Hilo, the product will be made available to US consumers in 2026.

Trusted by over 130,000 users globally, the Hilo Band has demonstrated the impact of Aktiia's technology in real-world settings. With this FDA clearance, consumers in the U.S. will soon have access to the same clinically validated innovation behind the Hilo Band and app. With no medical prescription required, it is now the first cuffless blood pressure monitor authorized for over-the-counter use in the United States. The milestone sets a new global benchmark for how blood pressure can be effortlessly monitored through wearable, user-friendly technology. With this FDA clearance, Aktiia is now positioned to establish Hilo as the category-defining wearable for cuffless blood pressure monitoring in the U.S. and beyond.

*“This is not just a regulatory win: it’s the start of a paradigm shift in hypertension management,” said Josep Sola, Co-Founder and CTO of Aktiia. “With FDA’s OTC clearance, we are breaking down the barriers that have kept cuffless blood pressure monitoring out of the hands of millions.”*

*“This milestone is the result of more than seven years of relentless scientific, clinical, and engineering effort,” said Mattia Bertschi, Co-Founder of Aktiia. “What began as a research vision in the Swiss Research Institute CSEM twenty years ago has now become the world’s first cuffless, FDA-cleared, over-the-counter solution for blood pressure – and we’re just getting started.”*

This regulatory clearance follows an oversubscribed Series B round of over \$42 million USD co-led earlier this year by Earlybird Venture Capital and Wellington Partners.

*“Aktiia’s FDA clearance represents a breakthrough moment for medical-grade wearables,” said Dr. Christoph Massner, Principal at Earlybird and Board Director of Aktiia. “We backed the team because they combined bold vision with scientific rigor; and today they’ve delivered what no one else could. The Hilo Band is poised to lead a global transformation in how we understand and manage cardiovascular health at scale.”*

The Hilo Band is not just another wearable: it is the first of its kind blood pressure companion, marking a breakthrough moment for cardiovascular health, much like the iPhone did for mobile technology. Due to its sleek, lightweight and comfortable form factor, the Hilo Band ushers in a new class of medical wearables that empower individuals to monitor their blood pressure anytime, anywhere. Achieving this milestone reinforces Aktiia’s leadership in cuffless, consumer-ready blood pressure monitoring, redefining what’s possible in everyday cardiovascular care.