U.S. FDA Grants Market Clearance for PyrAmes' Groundbreaking Boppli® Wearable Blood Pressure Monitor

Leading-edge medical device provides essential clinical value to newborns undergoing critical care

Boppli is designed to be a highly-advanced non-invasive blood pressure monitoring device that is ideal for neonatal infants in the NICU

Boppli offers safe and accurate BP monitoring as an alternative to invasive arterial lines (IAL) and intermittent cuff-based measurements

CUPERTINO, CALIFORNIA, UNITED STATES, October 10, 2023 /EINPresswire.com/ -- PyrAmes Inc., a digital health company pioneering innovative blood pressure (BP) monitoring solutions, has received FDA 510(k) clearance for its revolutionary Boppli® platform to safely and accurately monitor the blood pressure of critically-ill infants. Boppli offers continuous and non-invasive BP monitoring as an alternative to invasive arterial lines (IAL) and intermittent cuff-based measurements. Boppli previously received Breakthrough Device Designation from the U.S. FDA, recognizing its potential to enable more timely identification of life-threatening conditions. Boppli is the only commercially-available, continuous and non-invasive BP monitoring solution for infants.

Boppli improves ease of use and avoids the risks and costs associated with IALs. Boppli also eliminates the cumbersome and time-consuming nature of standard cuff-based measurements, which provide only occasional spot BP values and may be prone to inaccuracies.

Boppli accuracy was demonstrated to be within FDA guidelines during a rigorous, pivotal clinical study by comparing Boppli sensor data against simultaneous IAL data for critically ill infants in multiple neonatal intensive care units (NICU) in the U.S. and Canada.

“Boppli will provide us with the ability to non-invasively and continuously monitor blood pressure in our tiny, fragile babies – accurately and without disturbing them,” said Lamia Soghier, MD, MEd, MBA, Medical Director and Quality & Safety Officer of the NICU at Children’s National Hospital. “This is a game-changer, as we no longer have to worry about spending time sticking infants multiple times in multiple places to put in an arterial line. I am also excited that we will avoid arterial line complications. As a clinician who has seen terrible loss of fingers from thrombosis of arterial lines, I am thrilled that we now have a safer modality. We will be able to place Boppli quickly, even for our tiny 500g infants. As one of the centers in PyrAmes’ clinical study, we saw first-hand the value that Boppli provided to medical care in the NICU.”

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> *Lamia Soghier, MD, MEd, MBA, NICU Med. Dir. At Children’s National Hosp.*

Boppli integrates capacitive sensors that are placed on the arm and/or leg of infants to acquire pulse waveform measurements. The systolic, diastolic, and mean arterial pressures are then inferred from the recorded pulse waveform data using algorithms trained with artificial neural network techniques.

“We are excited to have Boppli, our company’s first product, cleared by the FDA,” said Xina Quan, Ph.D., PyrAmes Co-founder and CEO. “Detecting clinically-important blood pressure information in a safe and timely way with a non-invasive approach has the potential to provide life-changing clinical information for hundreds of thousands of fragile babies without the risks and costs of today’s standards of care.”

“As PyrAmes' commercial partner, we are excited to introduce these innovative products, empowering NICU doctors and nurses with Boppli's first-of-its kind Non-Invasive Blood Pressure technology," stated Bob Cormier, President of Sentec North America. "Boppli addresses a crucial need in non-invasive monitoring for neonatal patients, potentially transforming the well-being of these delicate, precious patients."

Boppli’s FDA market clearance represents a first step in PyrAmes’ robust product roadmap to enable more convenient, clinically-accurate, blood pressure monitoring for inpatients and

outpatients of all ages, beginning with babies and their mothers to support their health before and after childbirth.

About PyrAmes Boppli® and Bosimi™ Devices
PyrAmes devices are wearable bands designed to be versatile noninvasive blood pressure monitoring platforms for patients of all ages, ideal for infants in the NICU (Boppli) as well as women during and after pregnancy (Bosimi). They are intended to provide a safer option to arterial lines and a more convenient choice than standard blood pressure cuffs, and have the potential to revolutionize the standard of care for continuous blood pressure monitoring. PyrAmes' first commercial product, Boppli, is commercially available after FDA 510(k) clearance granted in September 2023.

About PyrAmes
PyrAmes is a digital health company focused on fundamentally transforming the delivery of health care through continuous blood pressure monitoring that is accurate, wireless, and noninvasive. The comfort and ease of use of its platform has the potential to provide better blood pressure management for patients ranging from newborns to seniors. The FDA has recognized the company's lead product Boppli with Breakthrough Device Designation and 510(k) market clearance. Bosimi products based on PyrAmes technology are under development and have not yet been cleared by the FDA for distribution.

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