***Source:*** *Biolinq Incorporated*

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# Biolinq Shine™ Granted De Novo Classification by U.S. FDA for the First Fully Autonomous, Needle-Free Glucose Sensor

*First glucose sensor with an integrated primary display that works with and without a phone*

*Establishes a new category of wearable glucose sensors for metabolic health*

SAN DIEGO, Sept. 25, 2025 (GLOBE NEWSWIRE) -- Biolinq Incorporated, a pioneering developer of precision multi-analyte biosensors to improve metabolic health, today announced the U.S. Food and Drug Administration has granted De Novo Classification for its lead product, Biolinq Shine™. With this classification, Biolinq has a clear path forward to scale a new generation of wearable sensors designed for comfort, simplicity, and global reach.

Initially marketed to people with type 2 diabetes who are not dependent on insulin, Biolinq Shine is the first wearable biosensor integrating glucose, activity, and sleep information in a single device with autonomous operation. A patch on the forearm provides real-time glucose feedback through a primary color-coded LED display, visible with or without a phone. Additional insights, such as activity and sleep trends, are available through a mobile app.

Unlike filament-based glucose sensors, Biolinq Shine eliminates the need for a subcutaneous introducer needle for sensor placement. Its microsensor array, manufactured using state-of-the-art semiconductor technology, is up to 20 times more shallow than conventional continuous glucose sensors. The simple user experience delivers a new level of user engagement and confidence in continuous glucose monitoring.

“The entire Biolinq team is thrilled about this regulatory milestone, which is a testament to the outstanding work by our team. We are grateful to the FDA for its rapid and rigorous review in establishing a new category of wearable biosensors,” said Rich Yang, CEO of Biolinq. “While we celebrate this tremendous milestone, we’ve only scratched the surface of what is possible with our multi-analyte-capable biosensor platform in supporting metabolic health for everyone.”

“Biolinq Shine is a first-of-its kind biosensor designed to support metabolic health for people with diabetes who are not dependent on insulin,” said Dan Bradbury, Chairman of Biolinq. “By automatically tracking glucose levels, physical activity and sleep information, this technology offers meaningful insights that can encourage healthier choices every day.”

The American Diabetes Association (ADA) guidelines highlight the importance of time-in-range (TIR) for glucose levels in optimizing metabolic health, recommending that individuals with diabetes endeavor to remain within a standard target glucose range at least 70% of the time. Achieving this target range can be challenging with infrequent and episodic glucose measurements. A new generation of continuous glucose sensors such as Biolinq Shine can be a valuable tool in managing metabolic health.

“As long-standing supporters and investors of Biolinq, Alpha Wave remains confident in their ability to deliver on a bold, innovative vision for biowearables,” said Rick Gerson, Chairman of Alpha Wave Global. “Biolinq is on the path to redefine how society thinks about cardiometabolic health and wellness, driving the next wave of innovation with a profound multi-analyte biosensor platform.”

**About Biolinq Incorporated**
Biolinq Incorporated is a healthcare technology company pioneering precision multi-analyte wearable sensors to improve metabolic health. The company’s biosensor platform is designed to inform and inspire with unparalleled simplicity to support healthier living. With microsensors that reside just below the skin's surface, Biolinq is redefining the future of continuous biosensing. The company is headquartered in San Diego, CA. For more information, please visit www.biolinq.com.

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