Sequel's twiist™ Automated Insulin Delivery System Receives FDA 510(k) Clearance

Device Bundles Latest Technology to Deliver Significant Advancements for Insulin Management for People with Type 1 Diabetes

MANCHESTER, N.H., (March 18, 2024) – Sequel Med Tech, LLC, a company developing state-of-the-art insulin delivery technologies, today announced its partner, DEKA Research & Development Corp., has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the innovative twiist™ Automated Insulin Delivery (AID) system powered by Tidepool. The twiist AID system, which will be commercialized by Sequel Med Tech, LLC, is the first drug delivery system that directly measures the volume and flow of insulin delivered with every micro-dose. Cleared for people ages 6 and up with type 1 diabetes, the twiist AID system offers the capability and flexibility to address each patient's individual dosing needs.

AID systems integrate data from a continuous glucose monitoring (CGM) device, a control algorithm, and an insulin pump to automate insulin delivery, providing patients with the ability to manage their blood sugar levels more effectively. The twiist AID system takes advantage of the FDA's medical device interoperability standards designed to help patients better tailor their treatments to their individual needs.

Image 1: Sequel twiist™ Automated Insulin Delivery (AID) system

"The clearance of the twiist AID system is a pivotal first step in Sequel's quest to make day-to-day life easier for people with type 1 diabetes. The twiist system combines drug delivery technology that directly and precisely measures each dose of insulin, providing the opportunity for better control and flexibility," said Sequel CEO and Co-Founder, Alan Lotvin, MD. "Sequel is working to simplify living with diabetes by introducing product and process innovation while expanding access for all. It's why we expect to distribute twiist through the pharmacy channel so more people with type 1 diabetes have a convenient, affordable way to get started on an AID system. As we get closer to launch, we will share more details about additional initiatives designed to expand access and simplify the patient experience."

The twiist system incorporates FDA-cleared Tidepool Loop technology, which enables the system to automatically adjust insulin delivery based on CGM readings and predicted glucose levels. Sequel chose to partner with Tidepool, a diabetes-focused non-profit organization, because the underlying technology is community driven, designed for and by people living with diabetes, provides individuals with a high degree of customization and most importantly - delivers the clinical results patients are looking for.

"There's been a real need for continued innovation in insulin delivery, and the twiist AID system powered by

Tidepool represents a substantial leap forward," said Howard Look, President and Chief Executive Officer of Tidepool. "The twiist AID system takes advantage of the Tidepool Loop algorithm, the first and only FDA-cleared glycemic controller that originated as a patient-led initiative. We are thrilled to see twiist come to market and bring new advancements to people living with type 1 diabetes."

The underlying drug delivery technology was developed by DEKA Research & Development Corp., birthplace of some of the most innovative and life-changing products of our time. DEKA was founded by Dean Kamen, an American inventor and entrepreneur who commercialized the first wearable insulin pump for diabetes, which he developed while still in high school. Kamen is a co-founder of Sequel and also created FIRST® (For Inspiration and Recognition of Science and Technology) and FIRST® Global, organizations dedicated to motivating the next generation to understand, use and enjoy science and technology.

"The FDA's clearance marks a transformative moment, and we would like to thank the FDA for their vision of interoperability in insulin delivery that will help improve diabetes therapies for years to come. The twiist system was designed from the start to integrate with the latest available innovation, and it represents the next generation of insulin delivery." said Kamen. "The twiist AID system reimagines how insulin is measured and delivered for more personalization with a simpler design. I believe the twiist AID system will set a new standard for precise, dependable insulin delivery going forward."

Type 1 diabetes is a lifelong condition that affects nearly 2 million Americans, in which the body's immune system destroys cells in the pancreas that make insulin. As a result, the pancreas makes little or no insulin, which prevents blood sugar from entering cells to make energy. People with type 1 diabetes must take insulin every day to stay alive.

You can learn more about twiist and sign up for updates at www.twiist.com.

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About Sequel

Headquartered in Manchester, N.H., Sequel Med Tech, LLC is developing the next generation of transformative drug-delivery advancements. Sequel's approach is to look at disease management holistically to advance systems that make living with disease simpler and easier for all. Its FDA-cleared innovation, the twiist® Automated Insulin Delivery (AID) system, integrates novel technologies to reimagine insulin delivery and sets a new standard for drug delivery. Co-founded by visionary Dean Kamen, serial entrepreneur Pablo Legorreta, seasoned medical device executive Bill Doyle and healthcare visionary Alan Lotvin, MD. Sequel is bringing the latest developments in science and technology to help drive more accessible drug delivery. For more information, visit sequelmedtech.com and twiist.com.