

Securisyn Medical Submits 510(K) to U.S. FDA for SolidAIRity™ III Airway Stabilization System

Highlands Ranch, CO — March 12, 2019 – Securisyn Medical, LLC, dedicated to inspiring the world to collaborate to make airway management safer, today announced the 510(k) Premarket Notification submission to the U.S. Food and Drug Administration (FDA) for its proprietary SolidAIRity™ III Airway Stabilization System. The Company’s 510(k) filing requests clearance of SolidAIRity™ III for commercial use in healthcare facilities that deliver care to mechanically ventilated patients in critical care areas such as Intensive Care Units (ICU), Operating Rooms (OR) and Emergency Departments (ED), as well as ground medical transportation entities.

Once the application has been accepted, the FDA will conduct its substantive review and may request additional information from the Company based on that review. FDA’s 510(k) review is 90 calendar days, not including time required by the Company to respond to additional information requests. The time required to respond to such requests will depend on the nature of the request.

“We are pleased to announce this important milestone, a key step in bringing the SolidAIRity™ III System to the ventilated patient market,” said Mark Bruning, President and Chief Executive Officer. Dr. Arthur Kanowitz, Founder and Chief Medical Officer added “Our FDA submission announced today is supported by non-clinical safety and performance data on the use of the SolidAIRity™ III Airway Stabilization System. We look forward to working with FDA throughout the review process and to achieving our goal of an FDA clearance that will lead to commercialization.”

About Securisyn Medical

Securisyn Medical, LLC (www.securisyn.com) headquartered in Highlands Ranch, Colorado, is an innovative medical technology and solutions company dedicated to creating and cultivating an approach to airway management that will enhance airway safety, prevent unplanned extubation and its associated complications, provide peace of mind for patients, their families, and practitioners and decrease healthcare costs through ethical, profitable, and sustainable business practices. The company is focused on collaborating with stakeholders around the world to eliminate preventable deaths related to airway management.

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