

HEMOSONICS AWARDED FDA 510(k) CLEARANCE FOR QUANTRA® HEMOSTASIS SYSTEM WITH QSTAT® CARTRIDGE

Next-Generation point-of-care whole blood hemostasis system now covers the broadest range of clinical indications in the U.S. to date

Durham, North Carolina – November 30, 2022 – [HemoSonics, LLC](#), a leading medical device company delivering individualized diagnostic solutions for Patient Blood Management (PBM), announced today that it has received 510(k) market clearance from the U.S. Food and Drug Administration (FDA) for the Quantra Hemostasis System with QStat Cartridge.

“The Quantra Hemostasis System with QStat Cartridge is breaking new ground and leading innovation in the point-of-care and laboratory-based whole blood hemostasis testing market. Today’s clearance significantly expands the clinical indications of the Quantra System, creating the greatest opportunity to address the critical unmet clinical needs of our healthcare provider partners and the patients that we serve,” said Robert Roda, President, and Chief Executive Officer of HemoSonics.

The FDA clearance of the QStat Cartridge expands the Quantra System’s indications for use to include trauma, and liver transplantation procedures. The QStat Cartridge assay, in addition to the System’s already established QPlus® Cartridge assay, increases Quantra’s overall diagnostic capabilities to now cover the broadest range of clinical indications of any point-of-care hemostasis analyzer available in the U.S. market today.

“Point-of-care data is the answer to PBM-guided patient decisions. It is a triple win; Patients get improved outcomes, public health is improved, and cost savings are achieved,” said Dr. Bruce Spiess, Medical Director of HemoSonics. “The Quantra Hemostasis System with QStat and QPlus Cartridges will assist more clinicians in determining which specific blood products are needed to rapidly treat individual patients. It has the potential to positively impact patient outcomes for hundreds of thousands of trauma patients and thousands of liver transplant recipients each year by optimizing blood product usage and conserving critically low blood supplies.”

The Quantra System leverages innovative SEER Sonorheometry, a proprietary medical-grade ultrasound technology, to measure the coagulation properties of a whole blood sample. The System enables clinicians to deliver patient-centered coagulation therapy that improves care

and optimizes blood product usage. With its rapid results, ease of operation, and dials screen for straightforward interpretation, the Quantra System is the only whole blood hemostasis testing system specifically cleared for use in point-of-care settings, such as operating rooms, emergency departments, and intensive care units.

“HemoSonics has recognized the specific needs of emergency departments and operating rooms. The Quantra Hemostasis System’s new QStat Cartridge provides fast, easy-to-interpret results that can improve individualized transfusion of blood products when time is critical,” said Dr. Ross Davenport, Senior Lecturer in Trauma Sciences and Consultant Vascular and Trauma Surgeon at the Royal London Major Trauma Centre, Bart’s Health NHS Trust.

Availability

The Quantra System with QPlus and QStat Cartridges is commercially available in the U.S., Europe, Australia, New Zealand, Japan, and Hong Kong.

For more information or to schedule a demonstration, please visit

<https://www.HemoSonics.com>.

About HemoSonics

HemoSonics, LLC is a medical device company with the primary mission to deliver clinical tools that provide actionable information in critical care settings, resulting in better care for patients and lower overall medical costs. The Quantra Hemostasis Analyzer, HemoSonics’ flagship product, is designed to improve patient outcomes and reduce healthcare costs by providing optimized coagulation information. The Quantra System’s easy and fast interpretation enables simple, more efficient point-of-care bleeding management. HemoSonics is part of the Stago group, a leading company in the *in vitro* diagnostics industry dedicated to exploring thrombosis and hemostasis. HemoSonics’ manufacturing, R&D, and Headquarters are based out of Durham, NC.

Contact

John Friedl
HemoSonics, LLC
949-485-0465
jfriedl@hemosonics.com