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Haemonetics Receives FDA Clearance for New TEG® 6s Global Hemostasis - HN Cartridge

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BOSTON, April 4, 2024 /PRNewswire/ -- Haemonetics Corporation (NYSE: HAE), a global medical technology company focused on delivering innovative medical solutions to drive better patient outcomes, announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the TEG® 6s hemostasis analyzer system Global Hemostasis-HN assay cartridge. This new cartridge extends Haemonetics' TEG 6s viscoelastic testing capabilities to serve fully heparinized patients in adult cardiovascular surgeries/procedures and liver transplantation in both laboratory and point-of-care settings.

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"TEG testing provides critical information that can help physicians improve hemostasis management for their patients, especially in critical situations like open heart and liver transplant surgeries and major trauma," said Jan Hartmann, MD, Senior Vice President and Chief Medical Officer at Haemonetics. "The Global Hemostasis-HN assay cartridge expands the benefits of TEG 6s system to patients on cardiopulmonary bypass or undergoing liver transplantation where heparin or endogenous heparinoids are present."

Understanding a patient's complete hemostasis status quickly can have a significant impact on clinical outcomes and use of blood products. Haemonetics' cartridge-based TEG 6s system provides clinicians a complete picture about a patient's coagulation profile, with faster, more detailed information for actionable results compared to conventional coagulation testing. The TEG 6s analyzer is supported by TEG Manager® software that enables remote real-time viewing of results throughout the hospital, as well as Interpretation Guidance with customizable alert messages. Haemonetics is planning to release the new Global Hemostasis-HN cartridge for TEG 6s system in the coming months.

The 510(k) clearance was supported by clinical data from a multi-center trial that included 335 patients undergoing cardiac bypass surgeries, interventional cardiology procedures or liver transplantations. An additional study was conducted using 164 healthy volunteers to establish the normal reference ranges for the test cartridge. Overall, over 5,500 clinical data points were used to demonstrate safety and effectiveness of the Global Hemostasis – HN assays.

"Our market-leading TEG 6s platform has helped Haemonetics make effective and efficient viscoelastic testing more accessible throughout the world," said Stewart Strong, President, Global Hospital at Haemonetics. "With our new cartridge we look forward to expanding the impact of our Blood Management Technologies franchise through increased adoption of TEG 6s, and helping more clinicians improve patient outcomes and standards of care."

About Haemonetics

Haemonetics (NYSE: HAE) is a global healthcare company dedicated to providing a suite of innovative medical products and solutions for customers, to help them improve patient care and reduce the cost of healthcare. Our technology addresses important medical markets: blood and plasma component collection, the surgical suite and hospital transfusion services. Haemonetics' Global Hospital business provides a range of solutions to address the needs of hospitals, including Interventional Technologies for electrophysiology and interventional cardiology, and Blood Management Technologies that include diagnostics to help inform treatment decisions, technologies to help avoid unnecessary allogeneic transfusions and solutions to help optimize management of blood products. To learn more about Haemonetics, visit **www.haemonetics.com**.

Cautionary Statement Regarding Forward-Looking Information

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements. Forward-looking statements in this press release may include, without limitation, statements regarding plans and objectives of management for the operation of Haemonetics, including statements regarding potential benefits associated with the TEG 6s hemostasis analyzer system Global Hemostasis-HN assay cartridge and Haemonetics' plans or objectives related to the commercialization of such product enhancement. Such forward-looking statements are not meant to predict or guarantee actual results, performance, events or circumstances and may not be realized because they are based upon Haemonetics' current projections, plans, objectives, beliefs, expectations, estimates and assumptions and are subject to a number of risks and uncertainties and other influences. Actual results and the timing of certain events and circumstances may differ materially from those described by the forward-looking statements as a result of these risks and uncertainties. Factors that may influence or contribute to the inaccuracy of the forward-looking statements or cause actual results to differ materially from expected or desired results may include, without limitation, product quality; market acceptance; the effect of global economic and political conditions; and the impact of competitive products and pricing. These and other factors are identified and described in more detail in Haemonetics' periodic reports and other filings with the U.S. Securities and Exchange Commission. Haemonetics does not undertake to update these forward-looking statements.

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