



AngioDynamics Receives FDA Breakthrough Device Designation for the AngioVac System for the Non-Surgical Removal of Right Heart Vegetation

August 15, 2023

Pivotal Milestone Accelerates Pathway to Specific Indication

LATHAM, N.Y.--(BUSINESS WIRE)--Aug. 15, 2023-- AngioDynamics, Inc. (NASDAQ: ANGO), a leading and transformative medical technology company focused on restoring healthy blood flow in the body's vascular system, expanding cancer treatment options and improving quality of life for patients, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device designation for the Company's AngioVac System for the proposed indications for use to include the non-surgical removal of vegetation from the right heart.

The FDA Breakthrough Device designation is designed to help patients gain timely access to medical devices that may provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions for which no approved or cleared alternatives exist.

"The FDA's recognition of the AngioVac System and its potential to provide a novel and innovative treatment pathway for the non-surgical removal of vegetation from the right heart represents a significant step in our journey to advance patient care," said Jim Clemmer, AngioDynamics' President and Chief Executive Officer. "The support of our physician partners continues to lead us in the development, study and application of this innovative technology to treat and manage critical medical conditions for a patient population with an unmet need."

The AngioVac System is an on-circuit aspiration system that uses a venous drainage cannula to remove thrombi or emboli during extracorporeal bypass for up to six hours. The system allows for the removal of thrombus and embolic material while minimizing blood loss via a recirculation of blood through the AngioVac extracorporeal (venovenous) bypass circuit. Target vessels for the thrombus/embolus extraction include, but are not limited to, the iliofemoral vein, Inferior Vena Cava (IVC), Superior Vena Cava (SVC) and Right Heart.

Under the Breakthrough Device designation, AngioDynamics will engage with the FDA to achieve this new expanded indication for the non-surgical removal of vegetation from the right heart. The accelerated pathway expedites assessment and review processes of the AngioVac System and allows for more interactive and timely communication with the FDA, efficient and flexible clinical study design, FDA review team support, Agency senior management engagement and priority review.

Learn more about the AngioVac System at [AngioVac.com](https://www.angiodynamics.com).

About AngioDynamics, Inc.

AngioDynamics is a leading and transformative medical technology company focused on restoring healthy blood flow in the body's vascular system, expanding cancer treatment options and improving quality of life for patients.

The Company's innovative technologies and devices are chosen by talented physicians in fast-growing healthcare markets to treat unmet patient needs. For more information, visit www.angiodynamics.com.

*Indications for Use: The AngioVac C20 and C180 is indicated for use as a venous drainage cannula and for removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to 6 hours. The AngioVac F18⁸⁵ is indicated as a venous drainage cannula for the non-surgical removal of thrombi or emboli during extracorporeal bypass for up to 6 hours.

The AngioVac Circuit is indicated for use in procedures requiring extracorporeal circulatory support for periods of up to six hours.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

For important AngioVac Cannula and Circuit risk information, visit:

AngioVac Cannula C²⁰ and C¹⁸⁰

<https://www.angiodynamics.com/about-us/risk-information/#bangiovaccann>

AngioVac Cannula F18⁸⁵

<https://www.angiodynamics.com/about-us/risk-information/#cangiovaccann1885>

AngioVac Circuit

<https://www.angiodynamics.com/about-us/risk-information/#cangiovac>

Safe Harbor

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements regarding AngioDynamics' expected future financial position, results of operations, cash flows, business strategy, budgets, projected costs, capital expenditures, products, competitive positions, growth opportunities, plans and objectives of management for future operations, as well as statements that include the words such as "expects," "reaffirms," "intends," "anticipates," "plans," "believes," "seeks," "estimates," "projects", "optimistic," or variations of such words and similar expressions, are forward-looking statements. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. Investors are cautioned that actual events or results may differ materially from AngioDynamics' expectations, expressed or implied. Factors that may affect the actual results achieved by AngioDynamics include, without limitation, the scale and scope of the COVID-19 global pandemic, the ability of AngioDynamics to develop its existing and new products, technological advances and patents attained by competitors, infringement of AngioDynamics' technology or assertions that AngioDynamics' technology infringes the technology of third parties, the ability of AngioDynamics to effectively compete against competitors that have substantially greater resources, future actions by the FDA or other regulatory agencies, domestic and foreign health care reforms and government regulations, results of pending or future clinical trials, overall economic conditions (including inflation, labor shortages and supply chain challenges including the cost and availability of raw materials), the results of on-going litigation, challenges with respect to third-party distributors or joint venture partners or collaborators, the results of sales efforts, the effects of product

recalls and product liability claims, changes in key personnel, the ability of AngioDynamics to execute on strategic initiatives, the effects of economic, credit and capital market conditions, general market conditions, market acceptance, foreign currency exchange rate fluctuations, the effects on pricing from group purchasing organizations and competition, the ability of AngioDynamics to obtain regulatory clearances or approval of its products, or to integrate acquired businesses, as well as the risk factors listed from time to time in AngioDynamics' SEC filings, including but not limited to its Annual Report on Form 10-K for the year ended May 31, 2023. AngioDynamics does not assume any obligation to publicly update or revise any forward-looking statements for any reason.

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