Surmodics Receives FDA 510(k) Clearance for Pounce™ Thrombus Retrieval System

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Next-generation technology provides easy, effective clot removal from peripheral arterial vasculature

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Sep. 23, 2020-- Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, announced it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for its Pounce™ Thrombus Retrieval System.

The Pounce Thrombus Retrieval System is intended for the non-surgical removal of thrombi and emboli from the peripheral arterial vasculature. Depending on the age and magnitude of the occlusion and the viability of the threatened limb, existing treatments for this condition may include catheter directed thrombolysis, surgical embolectomy, and/or percutaneous mechanical thrombectomy. In cases in which the occlusion has caused irreversible damage to the limb, acute limb ischemia can result in the amputation of a lower extremity.

The Pounce Thrombus Retrieval System is a mechanical thrombectomy device that facilitates thrombus removal in peripheral vasculature without the added expense or commitment to any additional, external capital equipment.

“The FDA 510(k) clearance of our Pounce Thrombus Retrieval System brings us one step closer to providing a technology that offers significant advances over the current treatment of complex, peripheral artery disease (PAD),” said Gary Maharaj, President and Chief Executive Officer of Surmodics. “This approval also demonstrates Surmodics' deep R&D capabilities and we are excited to ramp up our development efforts on new clinical applications for deep vein thrombosis (DVT), pulmonary embolism (PE) and ischemic stroke.”

The device is comprised of three components: a 5 Fr basket delivery catheter, a basket wire assembly, and a trumpet assembly. After the basket wire assembly is delivered distal to the location of the thrombus, two nitinol self-expanding baskets are deployed to collect and entrain the clot into a trumpet-shaped nitinol wire mesh. With the clot entrained, the trumpet assembly is then collapsed into a 7 Fr guide sheath through which the clot is withdrawn and removed from the body.

“The Surmodics team has done an excellent job finalizing the product design and advancing the Pounce Thrombus Retrieval System into a medical device that has the potential to change the treatment algorithm for arterial thrombectomy, ” said Gary Ansel, MD, Founder and former Chief Medical Officer of Embolitech, from which Surmodics acquired the technology and intellectual property behind the Pounce Thrombus Retrieval System. “By providing peripheral interventionalists with an innovative, non-surgical tool for treating arterial thrombotic occlusions, the Pounce Thrombus Retrieval System will serve an important clinical need and is a great fit with the Company’s focus on advancing therapies for peripheral artery disease.”

About Peripheral Artery Disease (PAD)

Worldwide, over 200 million people have PAD[1], a serious and underdiagnosed circulatory condition caused by build-up of arterial plaque, most commonly in the legs. Twelve to 20 percent of Americans over 60 years old have PAD[2], which increases risk of coronary artery disease, heart attack and stroke, and can impair the ability to walk. If left untreated, PAD can lead to gangrene and limb amputation.[3]

About Surmodics, Inc.

Surmodics is the global leader in surface modification technologies for intravascular medical devices and a leading provider of chemical components for in vitro diagnostic (IVD) immunoassay tests and microarrays. Surmodics is pursuing highly differentiated medical devices that are designed to address unmet clinical needs and engineered to the most demanding requirements. This key growth strategy leverages the combination of the Company’s expertise in proprietary surface technologies, along with enhanced device design, development, and manufacturing capabilities. The Company mission remains to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota. For more information, visit www.surmodics.com. The content of Surmodics’ website is not part of this press release or part of any filings that the company makes with the SEC.

Safe Harbor for Forward-Looking Statements

This press release contains forward-looking statements. Statements that are not historical or current facts, including statements regarding Surmodics’ strategy, the potential for providing a technology that offers significant advances over the current treatment of complex, peripheral artery disease, and the company’s plans to ramp up its development efforts on new clinical applications for deep vein thrombosis (DVT), pulmonary embolism (PE) and ischemic stroke are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties, and important factors could cause actual results to differ materially from those anticipated, including the factors identified under “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2019, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our website at https://surmodics.gcs-web.com and at the SEC website at www.sec.gov. Forward-looking statements speak only as of the date they are made, and we undertake no obligation to update them in light of new information or future events.

References:

1. Fowkes FGR, et al. Lancet 2013, 382(9901):1329-1340.
2. Centers for Disease Control and Prevention. Peripheral Arterial Disease (PAD) Fact Sheet. n.d. Web.
3. National Institutes of Health. What is Peripheral Artery Disease? n.d. Web.

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