Surmodics Sublime™ Guide Sheath Receives FDA 510(k) Approval

April 23, 2019

Guide sheath is the first of Surmodics' family of products designed for peripheral procedures accessed from the radial artery

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Apr. 23, 2019-- 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 Sublime™ guide sheath.

The highly flexible, proprietary Xtreme® braid-reinforced *Sublime* sheath is designed to resist kinking and maximize strength while retaining a low profile. The sheath will be available in 5Fr and 6Fr diameters, and 120cm and 150cm lengths. The entire working length of the guide sheath is Serene® hydrophilic coated to provide a lubricious surface. It is preloaded with a dilator and has a hemostasis valve with side arm for flushing. The dilators are available with .018" and .035" guide wire compatibility.

"Surmodics continues to make progress in the development of clinically important and innovative technologies," said Gary Maharaj, Surmodics President and CEO. "Our *Sublime* guide sheath will set a new standard for performance and enable the delivery of lower extremity interventions from the radial artery."

Radial artery access has been widely adopted for use in coronary procedures where devices have been developed to accommodate that need. The *Sublime* guide sheath is intended to introduce therapeutic or diagnostic devices into the vasculature, excluding the coronary and neuro vasculature. Radial access offers many benefits relative to femoral access including reduced puncture site bleeding complications, earlier ambulation, reduced length of hospital stay, and lower healthcare costs.[1]

The development of the Surmodics*Sublime* guide sheath is a step forward in the Company's strategy to be a provider of whole-product vascular solutions, including a family of radial access products. Surmodics has complete capabilities for design, development and high-volume manufacturing of a wide variety of highly differentiated balloon catheter and specialty catheter solutions.

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 whole-product solutions that are designed to address unmet clinical needs for its medical device customers 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 about beliefs and expectations regarding the Company's strategy to transform to a provider of whole-product vascular solutions, 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 (1) our ability to successfully develop, obtain regulatory approval for, and commercialize our proprietary products; and (2) 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, 2018, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our website at www.surmodics.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. Mason P, Shah B, Tamis-Holland JE, et al. An Update on Radial Artery Access and Best Practices for Transradial Coronary Angioplasty and Intervention in Acute Coronary Syndrome. A Scientific Statement from the American Heart Association. *Circ Cardiovasc Interv*. 2018;11:e000035,p 1-21.

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Source: Surmodics, Inc.

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