Surmodics Receives FDA 510(k) Clearance for Sublime™ Radial Access 0.014 RX PTA Dilatation Catheter

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Device designed to treat below-the-knee vessels from the radial arteries with industry's longest (250 cm) working length

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Aug. 5, 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 Sublime™ Radial Access 0.014 Rapid Exchange (RX) Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter.

The Sublime Radial Access 0.014 RX PTA Catheter allows below-the-knee access through a transradial approach by providing the longest working length (250 cm) on the market. Outer balloon diameters range from 2.0 mm to 4.0 mm with balloon lengths between 20 mm and 220 mm. The product joins the previously cleared Sublime Radial Guide Sheath within the company's Sublime Radial Access Platform and is designed to facilitate radial access for the treatment of above- or below-the-knee arteries.

"FDA 510(k) approval of the Sublime Radial Access 0.014 RX PTA Dilatation Catheter is another step forward in our strategy to become a provider of whole-product vascular solutions through the design, development and manufacturing of highly differentiated products," said Gary Maharaj, Surmodics President and CEO. "The continued expansion of our Sublime Radial Access Platform demonstrates our commitment to developing the transradial peripheral market space through the introduction of longer, lower-profile devices that fill unmet physician and patient needs."

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] Although transradial access has become a mainstream technique in percutaneous coronary interventions (PCI), it has been less widely adopted in peripheral interventions due to the limited availability of purpose-designed access and therapeutic devices.

The Sublime 0.014 RX PTA Dilatation Catheter is compatible with a 5 Fr guide sheath and is designed to provide the performance of an over-the-wire PTA catheter in an RX platform. Its proprietary reinforced shaft technology with flexible, kink-resistant construction and a tapered RX port transition are designed for optimal trackability and push through distal tortuosity.

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, 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. 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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