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OpSens SavvyWire Guidewire for TAVR Procedures Receives FDA Clearance

September 15, 2022—OpSens Inc. announced that it has received FDA 510(k) clearance for the SavvyWire guidewire for transcatheter aortic valve replacement (TAVR) procedures.

According to the company, the sensor-guided SavvyWire supports multiple steps over the same device without exchange, while delivering continuous, accurate hemodynamic measurements and display. The device is designed to support TAVR efficiency and lifetime patient management.

In May 2022, OpSens announced that data supporting the safety and efficacy of SavvyWire were presented by Josep Rodés-Cabau, MD, at the EuroPCR 2022 conference, and simultaneously published online by Dr. Rodés-Cabau, et al in *EuroIntervention* (2022;18:e345-e348). On April 26, the company announced Health Canada approval for the SavvyWire guidewire.

Louis Laflamme, President and Chief Executive Officer of OpSens, commented in the company's press release, "For OpSens, FDA clearance is a key milestone and an achievement, introducing an entirely new category of innovation to the structural heart device market segment. The SavvyWire has been designed to provide best-in-class valve delivery capability and improve workflow in the TAVR procedure.

"SavvyWire uniquely provides a three-in-one solution for stable aortic valve delivery and positioning, continuous accurate hemodynamic measurement during the procedure, and reliable left ventricular pacing without the need for adjunct devices or venous access."

He concluded, "We look forward to introducing physicians to the SavvyWire at the upcoming TCT meeting in Boston later this week and then initiating our limited market release of the product to a select number of physician thought-leaders during the coming weeks."

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