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Osprey angiogram dye injector gets FDA clearance

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Singapore: Osprey Medical received US FDA 510(k) clearance for its Avert System, which is designed to reduce the amount of dye injected and exposed to patients undergoing angiogram or diagnostic heart procedures.

In a pilot human clinical study, the Avert System was shown to reduce the amount of dye by up to 40 percent without compromising image quality. Utilizing the Avert System on patients significantly reduces the amount of dye used in these procedures.

Mr Mike McCormick, president, Osprey Medical, said that, "We are delighted to have achieved this important milestone. Avert was not yet part of our plans when we undertook our IPO in May 2012. Developing the Avert System and obtaining FDA clearance in such a short period of time is testament to the capabilities of our team at Osprey and potentially opens up further exciting opportunities for the company."

"We will shortly begin to commercialize Avert in a controlled manner to demonstrate awareness and adoption patterns among select key opinion leading physicians," he added.

Osprey is currently building product inventory and developing product labels to meet FDA requirements, and is finalizing its US sales plans. Upon completion of these activities, the company will begin a controlled US commercialization anticipated to commence in Texas during the fourth quarter of 2013.