>cantech letter

A Regulatory Hat-Trick: Opsens OptoWire Cleared for Sale in Japan, Europe, and now U.S

JUNE 15, 2015 BY HOGAN MULLALLY

This morning, Quebec City-based**Opsens (TSXV:OPS)** announced it had received FDA 510(k) clearance to market its fractional flow reserve (FFR) technology, OptoWire, in the United States. The 510(k) clearance comes on the heals of earlier regulatory clearances for OptoWire in Europe and Japan.

FFR is used by interventional cardiologists to assess the degree of occlusion or stenosis in coronary arteries. The U.S. market is dominated by St. Jude and to a lesser degree Philips, which recently acquired Volcano Corp. Both companies use electronic sensors in their FFR products, whereas OptoWire is the first FFR product to use optical sensors. In today's press release, Opsens cites the advantages of OptoWire versus the competition as "Its immunity to the adverse effects related to blood contact" and "easy and reliable connectivity that leads to reliable FFR measurements in extended conditions of use".

The real proof of the advantages of OptoWire will be determined by the pace of adoption by interventional cardiologists. However, Opsens has yet to tell investors how it plans to market OptoWire in the U.S. In fact, the company hasn't clearly stated how it will commercialize OptoWire in Europe either, and they received clearance, called a CE Mark, there in late 2014.

http://www.cantechletter.com/2015/06/a-regulatory-hat-trick-opsens-optowire-cleared-for-sale-in-japan-europe-and-now-u-s/