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FDA Designates VenoValve a Breakthrough Device

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Irvine, Calif.-based Hancock Jaffe Laboratories' VenoValve device has earned the FDA's Breakthrough Device designation.

VenoValve, which is about to undergo a pivotal U.S. trial, could potentially be used to treat approximately 2.4 million U.S. patients with severe chronic venous insufficiency in the deep veins of their legs, the company said.

Data from a first-in-human study of the device indicated that the average patient improvement in disease manifestations was 56 percent and average improvement in pain was 76 percent at one year postVenoValve surgery.