Innovate Healthcare
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FDA grants breakthrough device designation to new chronic venous insufficiency device

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Hancock Jaffee Laboratories, a California-based healthcare technology company focused on cardiac and vascular conditions, has received the FDA's breakthrough device designation for its VenoValve device for chronic venous insufficiency.

The company's first-in-human study, shared with the public in December 2020, found that VenoValve was associated with significant improvements in reflux, disease manifestations and pain following surgery. In addition, there were no material adverse events 30 days after implantation.

The company is now planning a new clinical trial, SAVVE U.S., that will enroll up to 75 patients. Enrollment should begin within the next 60 days.

"We are very pleased to have the opportunity to work with the FDA on an expedited basis as we try to bring relief to the millions of patients who suffer from deep venous CVI and who currently have no effective treatment options," Hancock Jaffe CEO Robert Berman said in a prepared statement. "The VenoValve significantly improved the lives of the patients in our first-in-human study, and we hope to replicate that success in our SAVVE U.S. clinical trial."

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