Leviticus Cardio announces FDA Breakthrough Device Designation for the Leviticus FiVAD

The FDA designated the Leviticus FiVAD as a "Breakthrough Device"

PETAH TIKVA, ISRAEL, ISRAEL, September 25, 2019 / EINPresswire.com/ -- The Leviticus Cardio Fully Implantable VAD (Leviticus FiVAD) System is intended for use for wireless LVAD pump powering, controlling and monitoring, thus eliminating the need for a driveline connection and enabling six hours of freedom from external LVAD accessories and hardware. Leviticus Cardio's wireless power transfer technology, combined with any existing Ventricular Assist Device (VAD) system, provides a new, robust, comprehensive hybrid solution for Chronic Heart Failure (CHF) patients.

The official submission to the FDA says that:
"The Leviticus FiVAD offers significant advantages over existing approved and cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the rate of infections (hence the need for hospitalization and/or repeat surgeries including device replacements), improve patient quality of life, facilitate patients' ability to manage their own care (such as through eliminating the need for driveline daily maintenance), and establish long term clinical efficiencies (reduced infection rates and improved physical fitness both contribute towards improved effectiveness). Furthermore, Leviticus FiVAD availability is in the best interest of patients."

"Our team is grateful that the FDA has recognized the potential value Leviticus FiVAD can provide patients and physicians by granting this Breakthrough Device Designation," said Michael Zilbershlag, CEO of Leviticus Cardio. "We plan to fully leverage the benefits of FDA Breakthrough Device Designation as we seek to accelerate the U.S. clinical and regulatory process with the goal of providing physicians and patients with the benefits of our novel device."

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