CATHWORKS™

NEWS RELEASE

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CathWorks FFR$_{angio}$™ System Receives U.S. FDA Clearance

Enables non-invasive, objective functional evaluation of multi-vessel coronary artery disease

KFAR-SABA, ISRAEL and ALISO VIEJO, CA (December 20, 2018) — CathWorks announced today that its FFR$_{angio}$™ System received United States Food & Drug Administration (FDA) 510(k) clearance. The FFR$_{angio}$ system demonstrated accuracy versus the invasive FFR wire in a blinded comparative study, FAST-FFR. The results of the FAST-FFR pivotal study were used to establish substantial equivalence of the FFRangio system.

The CathWorks FFR$_{angio}$™ System quickly and precisely delivers the objective FFR guidance needed to optimize PCI therapy decisions. FFR$_{angio}$ is derived from routine X-rays acquired during a diagnostic angiogram procedure, is non-invasive and performed intra-procedurally during coronary angiography, eliminating additional clinical risk, time and cost associated with invasive FFR. FFR$_{angio}$ provides a 3D reconstruction of the entire coronary tree with FFR values along each vessel.

Jim Corbett, CathWorks CEO said, "The FDA clearance of CathWorks FFR$_{angio}$ is a significant milestone for interventional cardiologists and the healthcare system overall. It is the first non-invasive device of its kind to receive FDA clearance for use during Percutaneous Coronary Intervention (PCI) assessment. The FAST-FFR study was carried out at 10 centers world-wide and evaluated more than 380 patients. The study demonstrated the clinical predictive value across a full range of coronary physiology, including complex lesion assessment in bifurcations and calcified lesions. FAST-FFR also demonstrated that the FFR$_{angio}$ system could perform non-invasive, objective, multi-vessel, physiologic measurements to support PCI decision making."

Dr. Ifat Lavi, CathWorks Chief Technology Officer, Guy Lavi, CathWorks President, and Prof. Ran Kornowski, Chairman of Cardiology at Rabin Medical Center in Israel, invented the CathWorks technology and founded the company six years ago. Following the 510(k) clearance, Dr. Kornowski commented, "When we first collaborated, we were trying to solve a real dilemma that interventional cardiologists faced. Doctors knew that conventional FFR provided valuable objective data, but that came with the cost, risk, and time, that ultimately restricted adoption. With the FDA clearance of CathWorks FFR$_{angio}$, we believe that we have accomplished our goal of providing doctors with objective data to inform their clinical decision-making without an additional intervention. We want to express our deep appreciation for the support of our clinical development partners in Israel, the United States, Europe and Japan in realizing this goal."

About CathWorks
CathWorks is a medical technology company focused on applying its advanced computational science platform to optimize PCI therapy decisions and elevate coronary angiography from visual assessment to an objective FFR-based decision-making tool for physicians. FFR-guided PCI decision-making is proven to provide significant clinical benefits for patients with coronary artery disease and economic benefits for patients and payers. The company's focus is specifically on bringing the CathWorks FFR$_{angio}$ System to market to provide quick, precise, and objective intraprocedural FFR guidance that is practical for every case. Learn more at cath.works. # # #