

NEWS RELEASE

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CATHWORKS FFR_{angio}™ SYSTEM FILES FDA 510(k) SUBMISSION

KFAR-SABA, ISRAEL (August 22, 2018) — CathWorks announced that it has submitted its CathWorks FFR_{angio}™ System to the United States Food & Drug Administration (FDA) for review and 510(k) market clearance.

The CathWorks FFR_{angio} System is the non-invasive FFR platform that quickly and precisely delivers objective multi-vessel physiologic measurements to cost-effectively optimize and confirm intraprocedural PCI therapy decisions. It is designed to deliver the objective FFR guidance needed to optimize percutaneous coronary intervention (PCI) therapy decisions for every patient.

The FDA 510(k) submission was filed on August 7, 2018. This submission was made possible following early, full enrollment of the FAST-FFR trial.

CathWorks CEO Jim Corbett said, “The FAME trials clearly demonstrated the clinical and economic value of FFR in PCI decision-making. We are confident that the CathWorks FFR_{angio} System meets a real need for patients and physicians, and we expect the system to make non-invasive, wire-free FFR possible in coronary angiograms; reducing wire-related risks and costs.”

Corbett went on to add, “We anticipate 510(k) market clearance by the end of 2018. Given the CathWorks System’s compatibility with major coronary angiogram platforms and a clear CPT code, we expect the system to start benefitting physicians and their patients very soon.”

The CathWorks FFR_{angio} System is in development and is not yet FDA cleared or available for sale within the United States.

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 today 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.

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