

NEWS RELEASE

CATHWORKS FFR_{angio}™ SYSTEM RECEIVES REGULATORY APPROVAL IN JAPAN

KFAR-SABA, ISRAEL & ALISO VIEJO, CA (December 10, 2019) — CathWorks today announced the approval of The CathWorks FFR_{angio}™ System by the Japan's Ministry of Health, Labour and Welfare (MHLW). The CathWorks FFR_{angio} System is a non-invasive diagnostic technology that is used at the time of a routine angiography. The CathWorks FFR_{angio} System transforms routine angiogram images into objective and comprehensive physiology information, including color-coded 3D renderings of blood flow in the heart's arteries to help physicians optimize coronary artery disease decision making, including whether a stent is needed.

The CathWorks FFR_{angio} System is also commercially available in the United States and Europe. It is non-invasive and performed intra-procedurally during coronary angiography without adding additional clinical risk or per procedure costs. The technology has the potential to positively impact a significant patient population in Japan, where heart disease is the second leading cause of death and coronary artery disease accounts for approximately half of these deaths.¹

“The MHLW's approval of The CathWorks FFR_{angio} System is another important milestone for CathWorks, physicians and patients. It is the first non-invasive device of its kind to receive Japan MHLW approval for use during Percutaneous Coronary Intervention (PCI) and to determine the optimal treatment for patients with coronary artery disease” said Jim Corbett, CEO of CathWorks. “With this approval in Japan, we are positioned to significantly expand our ability to help more clinicians optimize coronary artery disease therapy decisions non-invasively while reducing unnecessary invasive catheterizations and saving costs.”

ABOUT CATHWORKS

CathWorks is a medical technology company focused on applying its advanced computational science platform to optimize coronary artery disease 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. For more information, visit www.cath.works.

1 Iso H. Changes in Coronary Heart Disease Risk Among Japanese. Circulation.2008;118:2725-2729

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