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Japan approves CathWorks device for coronary artery disease patients

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The first non-invasive device of its kind to receive Japan PMDA and Ministry of Health, Labour and Welfare approval

Israel-based medtech company CathWorks has announced the approval of the fourth generation CathWorks FFRangio System by the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). The FFRangio System is also commercially available in the United States and Europe.

"The FFRangio System enables us to quickly perform a comprehensive physiologic assessment of coronary artery disease (CAD) without the need for invasive pressure wires or hyperemic agents, providing significant benefits to clinicians and patients," said Dr Yutaka Hikichi, Director, Heart Center, Saga-Ken Medical Center Koseikan. "The approval of the fourth-generation application offers significant automation and enhancements, further simplifying the utilization of the platform."

The CathWorks FFRangio System has been the first non-invasive device of its kind to receive Japan PMDA and Ministry of Health, Labour and Welfare (MHLW) approval for diagnosis of functional ischemia for patients with ischemic CAD. The fourth-generation application includes significant automation and enhancements, while offering the same exceptional 93% diagnostic accuracy when compared to invasive wire-derived FFR.

"The PMDA approval of the fourth generation CathWorks FFRangio System is another significant milestone for CathWorks, physicians and patients," said Ramin Mousavi, President and CEO of CathWorks. "With this approval, along with our recently announced strategic partnership with Medtronic that includes global co-promotion, we are well positioned to significantly expand our presence in Japan, making the FFRangio technology available to more physicians and patients. The FFRangio platform enables physicians to optimize the diagnosis and treatment of CAD, while eliminating unnecessary invasive wires and drugs, all while reducing cost."