IRADIMED CORPORATION Announces FDA 510(k) Clearance for MRidium® 3870 Infusion Pump System

WINTER SPRINGS, Fla., May 29, 2025 (GLOBE NEWSWIRE) — Iradimed Corporation (NASDAQ: IRMD), a global leader in innovative medical devices for MRI environments, today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for its next-generation MRidium® 3870 IV Infusion Pump System. This advanced, MRI-compatible infusion pump extends Iradimed's unique position as the world's only supplier of non-magnetic MRI infusion pump devices, established with our first-generation device in 2005.

The MRidium® 3870 is poised to strengthen Iradimed's leadership for MRI-compatible infusion, addressing growing demands for safe and reliable fluid delivery in diagnostic imaging. The MRidium® 3870 features a non-magnetic ultrasonic pump motor, non-interfering RF emissions, and non-ferrous components, ensuring seamless performance in high-magnetic-field environments. Building on Iradimed's legacy of innovation, this next-generation system introduces an enhanced, intuitive graphical touchscreen user interface and advanced safety features. The 3870 can operate independently or be combined with additional 3870 pumps to operate as a four-channel IV infusion pump system for critical care patients. The 3870 also features a modern drug library solution that accommodates multiple patient care area drug listing, facilitating use in a wide variety of MRI applications and patient needs. These 3870 enhancements address the evolving needs of healthcare providers, driving patient safety and workflow efficiency during MRI scans.

"We are thrilled to receive FDA 510(k) clearance for the MRidium® 3870, a milestone that underscores our commitment to advancing MRI-compatible medical technology," said Roger Susi, President and CEO of Iradimed Corporation. "This long-awaited clearance reflects our productive collaboration with the FDA to meet evolving and stringent regulatory requirements. The MRidium® 3870 empowers clinicians to deliver critical IV fluids and medications safely and predictably in MRI environments, improving patient outcomes and operational efficiency."

Iradimed plans a strategic rollout of the newly FDA-cleared MRidium® 3870 infusion pump with initial unit deployment to select healthcare facilities in the fourth quarter of 2025. Material shipments growing towards full commercial distribution will ramp throughout 2026.

About IRADIMED CORPORATION

IRADIMED CORPORATION is a leader in developing innovative Magnetic Resonance Imaging ("MRI") compatible medical devices. We design, manufacture, market, and distribute MRI-compatible medical devices, accessories, disposables, and related services.

We are the only known provider of a non-magnetic intravenous ("IV") infusion pump system

specifically designed to be safe for use during MRI procedures. We were the first to develop an infusion delivery system that largely eliminates many of the dangers and problems present during MRI procedures. Standard infusion pumps contain magnetic and electronic components that can create radio frequency interference and are dangerous to operate in the presence of the powerful magnet that drives an MRI system. Our patented MRidium® MRI-compatible IV infusion pump system has a non-magnetic ultrasonic motor, uniquely designed non-ferrous parts, and other special features to safely and predictably deliver anesthesia and other IV fluids during various MRI procedures. Our pump solution provides a seamless approach that enables accurate, safe, and dependable fluid delivery before, during, and after an MRI scan, which is essential to critically ill patients who cannot be removed from their vital medications and children and infants who must generally be sedated to remain immobile during an MRI scan.

Our 3880 MRI-compatible patient vital signs monitoring system has been designed with non-magnetic components and other special features to safely and accurately monitor a patient's vital signs during various MRI procedures. The Iradimed 3880 system operates dependably in magnetic fields up to 30,000 gauss, which means it can operate virtually anywhere in the MRI scanner room. The Iradimed 3880 has a compact, lightweight design, allowing it to travel with the patient from the critical care unit to the MRI and back, resulting in increased patient safety through uninterrupted vital signs monitoring and decreasing the amount of time critically ill patients are away from critical care units. The features of the Iradimed 3880 include wireless ECG with dynamic gradient filtering; wireless SpO2 using Masimo® algorithms; non-magnetic respiratory CO2; invasive and non-invasive blood pressure; patient temperature, and optional advanced multi-gas anesthetic agent unit featuring continuous Minimum Alveolar Concentration measurements. The Iradimed 3880 MRI-compatible patient vital signs monitoring system has an easy-to-use design and allows for the effective communication of patient vital signs information to clinicians.

For more information, please visit www.iradimed.com.

Forward-Looking Statements

This release and any oral statements made regarding the subject of this release contain forward-looking statements as defined under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical facts, that address activities that the Company assumes, plans, expects, believes, intends, projects, indicates, estimates or anticipates (and other similar expressions) will, should, or may occur in the future are forward-looking statements. The forward-looking statements are based on management's current belief, based on currently available information, as to the outcome and timing of future events. The forward-looking statements involve risks and uncertainties, including, among others, that our business plans may change as circumstances warrant.

Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date that they are made, which reflect management's current estimates, projections, expectations, or beliefs, and which involve risks and uncertainties that could cause actual results and outcomes to be materially different. Risks and uncertainties that may affect the future results of the company include, but are not limited to; potential disruptions in our limited supply chain for our products; the Company's ability to receive U.S. Food and Drug Administration ("FDA") 510(k) clearance for new products and product candidates; unexpected costs, delays or diversion of management's attention associated with the design, manufacturing or sale of new products; the Company's ability to implement successful sales techniques for existing and future products and evaluate the effectiveness of its sales techniques; additional actions, warnings or requests from the FDA or other regulatory bodies; our significant reliance on a limited number of products; a reduction in international distribution; actions of the FDA or other regulatory bodies that could delay, limit or suspend product development, manufacturing or sales; the effect of recalls, patient adverse events or deaths on our business; difficulties or delays in the development, production, manufacturing and marketing of new or existing products and services; and changes in laws and regulations or in the interpretation or application of laws or regulations.

Such forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other important factors, many of which are outside of the Company's control that could cause actual results to differ materially from the results discussed in the forward-looking statements. These risks, uncertainties, assumptions and other important factors include, but are not limited to, those included in Part II, Item 1A, "Risk Factors" of the Company's Quarterly Reports on Form 10-Q, and Part I, Item 1A, "Risk Factors" of the Company's Annual Report on Form 10-K for the year ended December 31, 2024, as well as those otherwise described or updated from time to time in our other filings with the U.S. Securities and Exchange Commission. You are cautioned not to place undue reliance upon any forward-looking statements, which speak only as of the date made, and the Company undertakes no commitment to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise.

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