

## **IRADIMED CORPORATION Receives FDA Clearance for MRI Compatible IV Infusion Pump**

WINTER SPRINGS, Fla., Dec. 19, 2016 — IRADIMED CORPORATION (NASDAQ:IRMD), today announced that it received U.S. Food and Drug Administration (“FDA”) 510(k) clearance for its MRidium 3860+ magnetic resonance imaging (“MRI”) compatible IV infusion pump system, including its Dose Error Reduction System (“DERS”) software feature.

The MRidium 3860+ MRI compatible IV infusion pump system provides a seamless approach that enables accurate, safe and dependable fluid delivery before, during and after an MRI scan, which is important to critically-ill patients who cannot be removed from their vital medications, and children and infants who must generally be sedated in order to remain immobile during an MRI scan.

The DERS software feature was designed for use with the MRidium 3860+ and incorporates the latest dosing safety features for patients. The DERS system enables users to create a unique drug library and establish nominal values and limits for dose and concentration for specified infusion protocols. With DERS, patient safety and user convenience are supported by user-programmed infusion hard limits (maximum and minimum) and soft limits (high and low limits that require user confirmation to exceed).

“I am very pleased to have 510(k) clearance of our MRI compatible IV pump and the DERS drug library software option, as it closes a process that has lasted for just over two years. Through this review, we have demonstrated that our IV pump and development processes meet the high standards established by FDA. Additionally, with this clearance behind us, we are now able to allocate our full resources to finalizing the development of our MRI compatible patient vital signs monitoring system and continue planning for its successful launch,” said Roger Susi, President and Chief Executive Officer of the Company.

### **About the MRidium 3860+ MRI Compatible IV Infusion Pump System**

The MRidium 3860+ MRI compatible IV infusion pump system has been designed with a non-magnetic motor, uniquely-designed non-ferrous parts and other special features in order to safely and predictably deliver anesthesia and other IV fluids during various MRI procedures. The MRidium 3860+ can operate dependably in the presence of 0.2T to 3T magnets and are fully operational up to the 10,000 gauss-line. This means they are highly versatile and can operate virtually anywhere in the MRI scanner room, including close to the MRI scanner. The MRidium 3860+ MRI compatible IV infusion pump system has a 10-key numeric input keypad making our system easy to accurately program and operate. Our pumping range of 0.1 mL per hour to 1,400 mL per hour provides a broad range of fluid flow control. Our broad range of infusion rates support differing patient needs including low levels for pediatric sedation, mid-levels for continued IV infusion of medications to critically-ill patients and high levels in

the event of emergency situations. Our MRidium 3860+ MRI compatible IV infusion pump system includes proprietary single-use IV tubing sets, a non-magnetic pole and a lithium battery. In addition, we offer optional upgrade systems including the 3865 Remote/Control, 3861 Side Car, Dose Error Reduction System and an SpO2 monitor.

## **About IRADIMED CORPORATION**

IRADIMED CORPORATION is the only known provider of non-magnetic intravenous (IV) infusion pump systems that are specifically designed to be safe for use during magnetic resonance imaging (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 which can create radio frequency (RF) 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 been designed with a non-magnetic ultrasonic motor, uniquely-designed non-ferrous parts and other special features in order 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 important to critically-ill patients who cannot be removed from their vital medications, and children and infants who must generally be sedated in order to remain immobile during an MRI scan.

MRidium is a trademark of IRADIMED CORPORATION.

For more information please visit [www.iradimed.com](http://www.iradimed.com).

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