

IRADIMED CORPORATION Announces FDA 510(k) Clearance for Neonatal Pulse Oximetry and Capnography Monitoring Using its MRI-Compatible Patient Vital Signs Monitor

WINTER SPRINGS, Fla., April 02, 2019 — IRADIMED CORPORATION (NASDAQ: IRMD), today announced that it received FDA 510(k) clearance for neonatal use of the pulse oximetry (“SpO2”) and Capnography (“CO2”) monitoring features of its 3880 Magnetic Resonance Imaging (“MRI”) compatible patient vital signs monitoring system.

“This 510(k) clearance allows for neonatal use of the SpO2 and CO2 features of the 3880 MRI-compatible patient vital signs monitor. With this clearance, the full capabilities of the 3880 MRI-compatible patient vital signs monitoring system are now available for use on all patients. Not only does this allow us to offer clinicians greater flexibility when using our monitor, it also strengthens our competitive position,” said Roger Susi, President and Chief Executive Officer of the Company.

About the 3880 MRI Compatible Patient Vital Signs Monitoring System

IRADIMED designed the 3880 MRI-compatible patient vital signs monitoring system using non-magnetic components and other special features enabling the safe and accurate monitoring of a patient’s vital signs during various MRI procedures. 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.

Additionally, the IRADIMED 3880 MRI-compatible vital signs monitoring system’s compact and lightweight design enables uninterrupted monitoring during transport, resulting in increased patient safety and decreasing the amount of time critically ill patients are away from critical care units.

Available features of the IRADIMED 3880 system include:

- Wireless ECG with dynamic gradient filtering;
- Wireless SpO2 using Masimo® SET algorithms;
- Non-magnetic respiratory CO2;
- Non-invasive blood pressure;
- Invasive blood pressure;
- Patient temperature;
- Advanced Masimo® multi-gas anesthetic agent unit featuring continuous Minimum Alveolar Concentration measurements.

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.

About IRADIMED CORPORATION

IRADIMED CORPORATION is a leader in the development of innovative magnetic resonance imaging (“MRI”) compatible medical devices. We are the only known provider of a non-magnetic intravenous (“IV”) infusion pump system that is 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 which 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 been designed with 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 important 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.

For more information please visit www.iradimed.com.

Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Act of 1995, particularly statements regarding our expectations, beliefs, plans, intentions, future operations, financial condition and prospects, and business strategies. These statements relate to future events or our future financial performance or condition and involve unknown risks, uncertainties and other factors that could cause our actual results, level of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. The risks and uncertainties referred to above include, but are not limited to, risks associated with the Company’s ability to receive an EC Certificate or CE Mark for our existing products, receive FDA 510(k) clearance for new products; unexpected costs, delays or diversion of management’s attention associated with the design, manufacture 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 by or requests from the FDA; our significant reliance on a single product; unexpected costs, expenses and diversion of management attention resulting from the FDA warning letter; potential disruptions in our limited supply chain for our 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; changes in laws and regulations or in the interpretation or application of laws or

regulations.

Further information on these and other factors that could affect the Company's financial results is included in filings we make with the Securities and Exchange Commission from time to time. All forward-looking statements are based on information available to us on the date hereof, and we assume no obligation to update forward-looking statements.

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