Merit Medical Receives 510(k) Clearance to Market the Merit Laureate Hydrophilic Guide Wire

GLOBE NEWSWIRE

Merit Medical Systems, Inc. (Nasdaq:MMSI), a leading manufacturer and marketer of proprietary disposable devices used primarily in cardiology, radiology and endoscopy, today announced that it has received 510(k) clearance from the Food and Drug Administration to market the Merit Laureate(R) hydrophilic guide wire.

In February 2012, Merit Medical received a warning letter from the FDA regarding modifications in the manufacturing process for which the FDA required additional information. Merit complied by filing a new 510(k) submission.

Merit discontinued sales of the Merit Laureate(R) during the review period in the United States, but continued to market the product, which is manufactured in Galway, Ireland, in international markets.

"We are pleased to conclude this process and provide this product immediately to our U.S. customers," said Fred P. Lampropoulos, Merit Medical's Chairman and Chief Executive Officer. "We believe this segment of the guide wire business offers substantial opportunity and intend to introduce additional hydrophilic wires upon regulatory clearance in the near future."

ABOUT MERIT
Founded in 1987, Merit Medical Systems, Inc. is engaged in the development, manufacture and distribution of proprietary disposable medical devices used in interventional and diagnostic procedures, particularly in cardiology, radiology and endoscopy. Merit serves client hospitals worldwide with a domestic and international sales force totaling approximately 165 individuals. Merit employs approximately 2,700 people worldwide with facilities in Salt Lake City and South Jordan, Utah; Angleton, Texas; Richmond, Virginia; Maastricht and Venlo, The Netherlands; Paris, France; Galway, Ireland; Beijing, China; Copenhagen, Denmark; and Rockland, Massachusetts.