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## Milestone Medical Files 510(k) Application for Marketing Clearance of the Epidural Instrument and Disposables in the United States

Announces plans to submit results of clinical trials to leading industry journal for publication

**LIVINGSTON, NJ, July 21, 2016 -- Milestone Medical Inc. (WAR:MMD)** today announced it has filed its 510(k) application with the U.S. Food & Drug Administration (FDA) for marketing clearance of its epidural instrument and disposables in the United States.

As previously announced, the Company completed its COMPASS Study (CompuFlo® Assessment Study), a randomized, controlled, parallel group, multicenter, pivotal study to assess the safety and effectiveness of the epidural space verification with the CompuFlo® Epidural Computer Controlled System. The clinical trial for the epidural instrument reached an enrollment of 400 patients and consisted of two separate arms: (i) pain management; and (ii) labor and delivery. Both arms were compared against the current medical standards of care. The goal of the pivotal Investigational Device Exemption (IDE) clinical trial was to demonstrate the accuracy of the CompuFlo technology in identifying and confirming the epidural space location.

The Company also announced plans to submit the final data from the COMPASS Study including the results of the labor and delivery arm to a leading industry journal for publication. Interim data from the pain management arm of the study was presented in the U.S. at the American Society of Regional Anesthesia and Pain Management, and American Pain Society annual meetings. Additional interim data from the pain management arm was recently presented at the European Society of Anesthesiology annual meeting in London on May 28-30th.

Leonard Osser, Chief Executive Officer of Milestone Medical, stated, "We are pleased to submit our 510(k) application on the heels of completing our clinical trials in the United States. Having completed these trials, we are now accelerating our efforts to enter into domestic and international distribution agreements in advance of FDA marketing clearance. It is important to note, this study was designed to support not only submission to the FDA, but also facilitate U.S. reimbursement submissions as well as worldwide marketing."

## **About Milestone Medical Inc.**

Milestone Medical, Inc. has developed epidural and intra-articular drug delivery systems based on a patented, painless, computer-controlled injection and drug delivery technology originally developed by Milestone Scientific, Inc. Development of both the epidural and intra-articular instruments is now complete and the Company is currently pursuing regulatory approval for both instruments in the U.S. Milestone Medical received CE Mark approval to sell and market its intra-articular and epidural instruments across European Union. For more information please visit <a href="https://www.medicalmilestone.com">www.medicalmilestone.com</a>.

## Safe Harbor Statement

This press release contains forward-looking statements regarding the timing and financial impact of Milestone's ability to implement its business plan, expected revenues and future success. These statements involve a number of risks and uncertainties and are based on assumptions involving judgments with respect to future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond Milestone's control. Some of the important factors that could cause actual results to differ materially from those indicated by the forward-looking statements are general economic conditions, failure to achieve expected revenue growth, changes in our operating expenses, adverse patent rulings, FDA or legal developments, competitive pressures, changes in customer and market requirements and standards, and the risk factors detailed from time to time in Milestone's periodic filings with the Securities and Exchange Commission, including without limitation, Milestone's Annual Report for the year ended December 31, 2015. The forward looking statements in this press release are based upon management's reasonable belief as of the date hereof. Milestone undertakes no obligation to revise or update publicly any forward-looking statements for any reason.