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For Immediate Release:

EMS to Assist USGAO and FDA in the Spirit of Good Corporate Citizenship

(Dallas, TX: March 10, 2009) In response to the United States Government Accountability Office's report to Congressional Addressees in January 2009, Electro Medical Systems Corporation of Dallas, Texas has voluntarily agreed to provide greater transparency into its regulatory processes with FDA. EMS has submitted data it hopes will assist the agency in issuing regulation either reclassifying or requiring PMA's for Class III devices currently allowed to receive clearance for marketing via the 510(k) process. This action protects the intellectual property rights and market access afforded to EMS.

The GAO report, titled: FDA Should Take Steps to Ensure That High-Risk Device Types are Approved through the Most Stringent Premarket Review Process, recommends that FDA "expeditiously" takes the necessary action mentioned above to make certain that manufacturers of *high-risk* device types provide the evidence needed to ensure that a device is safe and effective before entering the U.S. marketplace.

Claims of politics taking precedence over science, greater demands of an FDA with fewer available resources, and misleading submissions, have all contributed to devices finding themselves approved for sale in the U.S. without the evidence to substantiate the clinical assertion(s) their manufacturers make.

Rocco DePace, Managing Director for Electro Medical Systems Corporation believes that "validating the clinical claims of our shockwave technology platform is the responsibility of EMS. FDA has provided us with regulatory framework and oversight. As good corporate citizens, we will maintain the integrity of the Swiss DolorClast® in the U.S. marketplace by whatever means is made available, and we will do so vigorously".

EMS believes that the Investigational Device Exemption (IDE) study is important to the public health. It is a voluntary request for FDA to access your manufacturing and business practices. If a medical device manufacturer knowingly takes measures to avoid an IDE, they are not only violating federal law, but are also withdrawing from the scientific process.

Electro Medical Systems Corporation is located in Dallas, Texas. As a global market leader, EMS has set industry standards for researching and developing micromechanical medical and dental prophylaxis devices of unequalled quality since 1981.