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AdvaMed Praises Legislation to Streamline *De Novo* Process, Finalize Classification of Pre-Amendments Devices

WASHINGTON, D.C. – Stephen J. Ubl, president and CEO of the Advanced Medical Technology Association (AdvaMed), released the following statement today in support of the “Improving Safety, Efficiency & Transparency in Device Regulation Act.” sponsored by Sen. Bob Casey, Jr. (D-PA) and Sen. John McCain (R-AZ):

“AdvaMed praises Sens. Casey and McCain for introducing legislation designed to improve the FDA clearance process and ensure American patients have timely access to safe and effective medical devices.

“We strongly support the need to strengthen and optimize the *de novo* process through a well-defined regulatory pathway, which will benefit the agency, industry and patients. This bill saves time and resources by eliminating the requirement that companies submit a 510(k) for technologies and receive a ‘Not Substantially Equivalent’ determination when they know going in there is no predicate device for their technology that could be used as the basis of a 510(k) determination. Eliminating this unnecessary step will make the process more efficient. We believe the under-utilized *de novo* process has the potential to play a key role in the regulation of medical devices. “AdvaMed also supports the need for FDA to make final classification determinations for the remaining Class III device types that pre-dated the 1976 Medical Device Amendments. AdvaMed has long called for FDA to expeditiously to complete this process. We believe these devices should be regulated commensurate with their risk profile: either reclassified into Class I or Class II or required to obtain PMA approval.

“AdvaMed looks forward to working with Sens. Casey and McCain, along with other members of Congress from both sides of the aisle and the FDA on these important issues.”

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AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. For more information, visit www.advamed.org.