FOR IMMEDIATE RELEASE
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AdvaMed Applauds Introduction of Legislation to Streamline *De Novo* Classification Process

WASHINGTON, DC – Stephen J. Ubl, president and CEO of the Advanced Medical Technology Association (AdvaMed), released the following statement today in support of new legislation introduced by Sen. Scott Brown (R-Mass.) to improve the *de novo* classification process for medical technology:

"We applaud the introduction of S. 1943 to streamline the *de novo* classification process for novel low- to moderate-risk medical technology. 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 into the classification, that there is no predicate technology. 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.

"We look forward to working with Sen. Brown and Sen. Kelly Ayotte (R-N.H.), members of Congress on both sides of the aisle, and FDA toward our shared goal of improving the device approval process."

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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.