

*** EMBARGOED UNTIL 9:00 AM EST, FRIDAY JULY 29, 2011 ***

MDMA Statement on IOM's 510(k) Report

WASHINGTON, DC – MDMA President and CEO Mark Leahey issued the following statement regarding the Institute of Medicine's (IOM) report on the "Public Health Effectiveness of the FDA 510(k) Clearance Process:"

"MDMA will continue to closely examine this report, and we are pleased that the IOM recognizes the crucial role medical devices have in patient care and their strong safety record," said MDMA President and CEO Mark Leahey. "We remain concerned about efforts to overhaul a regulatory pathway that would create additional uncertainties and slow patient access to medical therapies.

Moving forward, we will continue to work with FDA and all stakeholders to ensure a more predictable and reasonable process is in place."

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