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MITA: IOM OFFERS WRONG APPROACH TO ONGOING 510(K) REFORM EFFORT

Rosslyn, Va. – Following an initial review of the Institute of Medicine’s (IOM) 510(k) report released this morning, MITA is concerned and disappointed by the recommendation to completely abandon the current device clearance process and design an entirely new regulatory framework. MITA is hopeful that these conclusions will not distract from the ongoing efforts to improve the existing 510(k) review process.

“The 510(k) reform effort has been underway for well over a year and IOM’s recommendations come very late in the process, falling far outside of the current conversation,” said Dave Fisher, executive director of MITA. “The 510(k) process has a proven record of bringing safe and effective technologies to market in a timely manner.”

Despite recent delays and challenges, the Food & Drug Administration’s 510(k) review process has provided patients with access to safe and innovative devices, including advanced imaging technologies. Recent studies have demonstrated that the process is extremely successful in the protection of public health, with less than 0.5 percent becoming the subject of a Class I safety recall, often due to post-marketing quality system issues, not premarket approval.

“Manufacturers have been working with the FDA and the broader imaging community to identify and implement targeted and effective improvements to the 510(k) review process,” Fisher continued. “It is imperative that this effort continue. The IOM has offered the wrong approach.”

For more than a year, the FDA has issued reports and published new standard operating procedures, guidances and regulations. MITA and many other stakeholders have been fully engaged in the FDA’s efforts and have provided detailed and comprehensive comments.

“American jobs and patient access to life-saving technologies are at stake,” said Fisher. “We need to build on the current 510(k) process by implementing reforms that further promote innovation, enhance regulatory predictability, improve timeliness and protect public health. MITA remains committed to working with the FDA and Congress to achieve these goals.”