July 26, 2019

Ms. Vanessa Countryman  
Secretary  
Securities and Exchange Commission  
100 F Street NE  
Washington, DC 20549-0609

RE: File No. S7-06-19: Amendments to the Accelerated Filer and Large Accelerated Filer Definitions

Dear Ms. Countryman:

The Advanced Medical Technology Association (“AdvaMed”) is pleased to provide the following comments to the Securities and Exchange Commission (SEC) on File No. S7-06-19, its proposed rule to amend the definitions of “accelerated” and “large accelerated” filers.

The Advanced Medical Technology Association (AdvaMed) is the world’s largest trade association representing medical device and diagnostics manufacturers. AdvaMed’s member companies produce the innovations that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed has more than 400 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers. AdvaMed Accel is the division within AdvaMed dedicated to addressing the unique needs and challenges of these smaller medical device and diagnostics manufacturers – the lifeblood of the medical technology industry. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

The medical technology industry is heavily skewed toward small companies—the kind of companies that begin with a scientist, engineer, or doctor with an idea to improve patient care. More than two-thirds of the medical technology firms in the U.S. have fewer than 20 employees, and a high proportion of the breakthrough products in our industry come from these small, often venture-capital funded companies. The long-term health of the whole industry depends on the continued success of these small firms and their access to the capital necessary to develop the breakthrough products of the future. Access to this capital is further dependent on the ability of investors to recoup their investment through an exit event (an IPO being one important path) – allowing for reinvestment and continued capital flow into this important industry.

However, in recent years, the regulatory environment for public companies has deterred innovators from accessing capital through IPOs, resulting in a disproportionate decline in small public companies. This has negatively impacted the medtech innovation ecosystem. Pre-commercial IPOs in the medtech industry are still very rare. Medtech companies are advised that they should generate $20-$30 MM in
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revenue for a successful IPO to occur (recent average of $41 MM), placing the burden on private capital sources to advance these technologies far into a commercial state; exit options are then somewhat limited, thereby stagnating the flow of capital. Decreasing the costs and complexity of regulatory burdens for small public companies by amending the accelerated filer and large accelerated filer definitions will help reverse this trend, as well as make the public markets a more viable option for growth companies. Accordingly, the thoughtful and targeted regulatory changes proposed by the Commission will improve the attractiveness of the public markets for small companies.

The proposed rule will expand the universe of small public companies that are exempt from Sarbanes-Oxley (SOX) 404(b), the auditor’s attestation of internal controls over financial reporting, to companies with annual revenues of less than $100M. While well-intentioned, SOX 404(b) has harmed small public companies because of its significant expense, which is borne disproportionally by small companies. These costs redirect capital from productive uses that would grow businesses and towards regulatory compliance, which is of little use to investors. We strongly believe that this proposed rule will benefit the broader medtech ecosystem by freeing up more capital for small companies to invest in research and human capital, improving their ability to innovate and build successful companies, while maintaining other key protections from the Sarbanes-Oxley Act of 2002.

If the United States is to remain competitive, there must be policies in place to incentivize financial investment in promising next-generation medical technology companies to create breakthrough products and high-quality jobs. We commend the SEC’s efforts to ease the regulatory burdens facing small companies and believe this change will encourage more emerging growth companies to go public and access the capital necessary to create jobs, grow the economy, and preserve America’s role as the leader in medical technology innovation.

If you have further questions or comments, please contact me.

Sincerely,

Ashley Wittorf