



AdvaMed

Advanced Medical Technology Association

MDUFMA Stakeholders Meeting – Performance Goals

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- Mandated under 2002 Medical Device User Fee and Modernization Act (MDUFMA)
 - Intent was to reduce the amount of time from submission to market
 - Includes decision goals and cycle goals
- FDA met most of 2005 Performance Goals
 - AdvaMed commends FDA for this achievement



- Does Current Process Achieve the Original Intent?
 - FDA Response: In some cases and some cases unintended consequences
 - Industry Response: Very Infrequently



- Industry Perspective

- Substantial increase in non-approvable letters for PMA Supplements
 - ✓ FY 2003: 31 out of 203 or ~ 15%
 - ✓ FY 2004: 43 out of 103 or ~ 42%
 - ✓ FY 2005: Not available, suspect it may be higher
- Increase in not-substantially equivalent (NSE's) decisions for 510 (k) submissions



- Path Forward

- 💡 More guidance documents needed
 - Release of PMA Change Guidance document will provide transparency on what type of submission is required
- 💡 AdvaMed willing to work in a collaborative manner to develop innovative ways to improve process