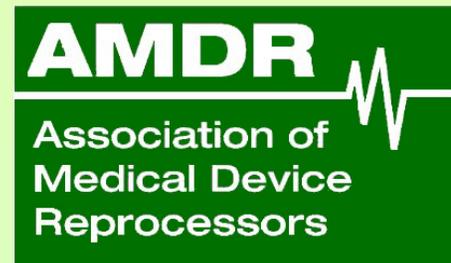


FDA MDUFMA Stakeholder Meeting

AMDR Presentation

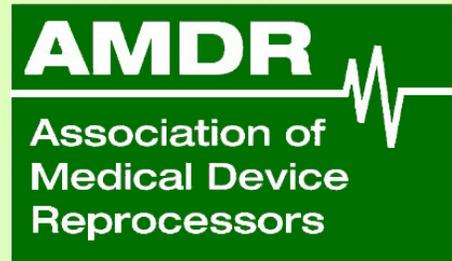
November 17, 2005

Gaithersburg, MD



“Pre-MDUFMA” Background

- Reprocessors were subject to the same regulatory requirements as OEMs
- 20+ year stellar safety record, 30 million+ devices
 - Embraced by the top hospitals
 - No evidence of increased risk to patients.

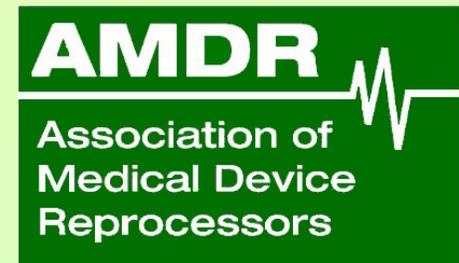


Why MDUFMA?

- No public health rationale for additional requirements
- Continued OEM frustration with economic threat posed by reprocessing
- “[W]e want to ensure access to safe and effective reprocessed devices.”

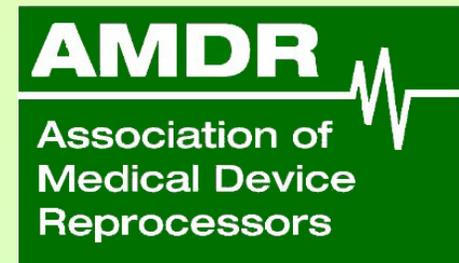
House Report 107-728, at 44.

- Least burdensome implementation



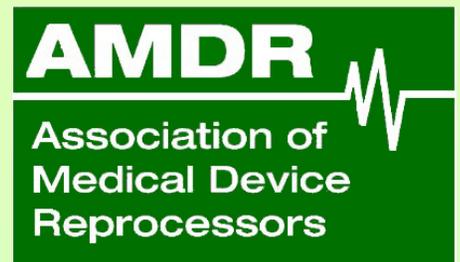
What's Happening Now

- Reprocessors are complying with MDUFMA's requirements
- Supplemental Validation Submissions
 - Approximately 95 percent of products remain legally marketable.
 - Additional submissions are under review.
 - Patient safety is not an issue!



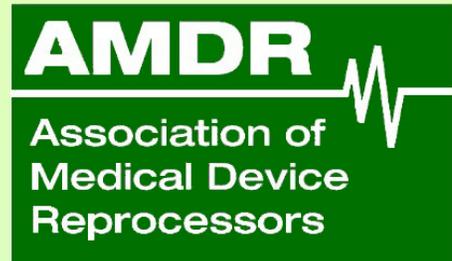
What's Happening Now

- Amendment of section 301
- OEM petitions to add devices to List I and List II
- Anti-reprocessing legislation at the state level
- Broad-based anti-reprocessing media campaign



Reprocessing is Here to Stay

- Despite the enormous efforts to eliminate reprocessed devices as an option for hospitals, the third-party reprocessing industry is growing, and is continuing to provide hospitals with a safe, effective way to achieve cost savings.



Benefits of Reprocessing

- Enables hospitals to save money without compromising patient care
 - Savings are used to improve patient care
- Reduces the medical waste stream
- Provides competitive pressure on price of original devices

