

MDUFMA STAKEHOLDERS MEETING

PRESENTATION BY
ROBERT BRITAIN

VICE PRESIDENT MEDICAL PRODUCTS

NATIONAL ELECTRICAL
MANUFACTURERS ASSOCIATION

NOVEMBER 17, 2005

FDA Performance on Product Clearance Processes

- 510(k) clearance process is working well
- Review of 510(k)s usually less than 90 days
- Third party review times are comparable to FDA review times