AdvaMed
Advanced Medical Technology Association

NEMA

MDMA

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This document reflects a joint understanding regarding the FY 2007 180-day PMA decision goal between the Food and Drug Administration (FDA) and the three industry organizations that worked with FDA and Congress to develop the Medical Device User Fee and Modernization Act of 2002 (MDUFMA): the Advanced Medical Technology Association (AdvaMed), the Medical Device Manufacturers Association (MDMA), and the National Electrical Manufacturers Association (NEMA) ("the industry representatives").

MDUFMA sets out a framework under which fees paid by the medical device industry would augment increased appropriations to provide FDA with sufficient resources to conduct its review of medical device applications in a more timely way. The performance goals for the review of medical device applications are contained in a November 14, 2002 letter from Health and Human Services Secretary Tommy Thompson ("Goals Letter").

The Goals Letter includes a goal for FDA to make an "FDA decision" within 180 days on 50% of PMAs and panel-track PMA supplements received in FY 2007. FDA and the industry representatives agree that, for FY 2007, FDA will manage its resources towards meeting the 180-day decision goal rather than the 150-day cycle goal for PMAs. FDA and industry understand that this focus on the 180-day decision goal may mean the agency does not meet the 150-day cycle goal.

Sincerely yours,

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