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AdvaMed
Advanced Medical Technology Association

AdvaMed's Comments
at the
Open Public Session, Annual Stakeholder Meeting
on the
Implementation of the Medical Device
User Fee and Modernization
Act of 2002 (MDUFMA)

by

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Hilton Washington DC North/Gaithersburg
Gaithersburg, Maryland

ABSTRACT

AdvaMed appreciates this opportunity for additional industry input to the December 3, 2003 MDUFMA Stakeholder meeting. AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,100 members manufacture nearly 90 percent of the $75 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $175 billion purchased annually around the world.

AdvaMed was actively involved in the development of MDUFMA, and in the negotiations that resulted in the premarket review performance goals that are so critically important to our members. We are gratified at the high priority that FDA has placed on implementation of the MDUFMA provisions, and we would like to thank FDA staff for its hard work.

AdvaMed wants to ensure that the many important provisions of MDUFMA are implemented according to the statute's original intent, and that the premarket review performance goals are met. Our members will make presentations at each of the five stakeholder panels and several issues will be reiterated here, including appropriations and user fees, the importance of transparency, and our determination to ensure the success of MDUFMA.