



August 27, 2010

Philip Desjardins
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave.
Building 66 Room 5447
Silver Spring, MD 20993-0002

RE: Docket No. FDA-2010-N-0348

Dear Mr. Desjardins,

On behalf of 60 medical device manufacturers and associated business members of the Indiana Medical Device Manufacturers Council (IMDMC), we respectfully request a 30-day extension of the comment period for the docket referenced above – CDRH 510(k) Working Group Preliminary Report and Recommendations, and Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations.

Indiana is one of the world leaders in the medical device industry. In fact, according to the U.S. Census, Indiana is the 2nd largest state in the value of medical device products shipped. A wide variety of medical device manufacturers employ approximately 19,950 Hoosiers across the state, with a payroll of more than \$1 billion ranking Indiana 7th in the nation in terms of medical device sector employment.

The IMDMC supports the efforts of FDA to assess and improve the 510(k) process. We welcome the opportunity to comment on the findings and recommendations documented in the CDRH Preliminary Internal Evaluations reports and are working to draft comments that we believe the CDRH will find helpful. Given the length of the reports and the numerous recommendations reflecting significant new requirements for many of our members, we are concerned that the published comment period does not allow adequate time to draft comments reflecting our members' perspectives. Therefore, we request a 30-day extension to the comment deadline of October 4 to allow us the time needed to provide constructive feedback. Thank you for your consideration of our request.

Sincerely,

Danelle R. Miller
IMDMC President

Regulatory Counsel,
Roche Diagnostics Corporation

IMDMC Board Member Companies

*Anson Group, Baker & Daniels, Bayer Diabetes Care, Biomet Inc., Cook Inc., DePuy Orthopaedics,
Eli Lilly and Company, Hill Rom, Inc., Johnson & Johnson Inc., Medtronic Inc., Roche Diagnostics Corp., Zimmer Inc.*

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