DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

January 16, 2013

Mark E. Du Val
Du Val & Associates, P.A.
1820 Medical Arts Building
825 Nicollet Mall
Minneapolis, MN 55402

Dear Mr. Du Val:

Your Citizen Petition and Petition for Stay of Action to the Food and Drug Administration on behalf of Minnesota Medical Device Alliance requesting the Commissioner to stay the implementation of "Draft Guidance for the 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications", dated December 27, 2011, was received by this office on 1/16/2013. It was assigned docket number FDA-2013-P-0076/CP1, and it was filed on 1/16/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)