DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JUL - 3 2013

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

Re: Citizen's Petition – Docket Number FDA-2013-P-0076/CP1

Dear Mr. DuVal:

This is an interim response to your citizen petition dated January 2, 2013, which was filed by the Food and Drug Administration (FDA) on January 16, 2013, and filed concurrently with a petition for stay of action. In your petition for stay of action, on behalf of Minnesota Medical Device Alliance, you requested the Commissioner of Food and Drug stay implementation of the final version of the document "Draft Guidance for Industry and Food and Drug Administration Staff – The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," issued on December 27, 2011. In your citizen petition, you request, among other things, that FDA" revert" to the use of the 510(k) guidance documents currently in existence until FDA has taken the steps that you outline in your citizen petition.

FDA has been unable to reach a decision on your citizen petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen's petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Loretta Chi of our Regulations Staff at (301)796-5847.

Sincerely yours,

Nancy Stade
Deputy Director for Policy
Center for Devices
and Radiological Health