



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

February 15, 2013

Richard M. Karcich

exemption 6

Dear Mr. Karcich:

Your petition to the Food and Drug Administration requesting to issue new regulations or amend existing regulations for measuring the reliability of software in medical devices, was received by this office on 2/15/2013. It was assigned docket number FDA-2013-P-0199/CP1, and it was filed on 2/15/2013. 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)