

Food and Drug Administration
Rockville MD 20857

FILE COPY

January 28, 1997

David F. Weeda
Olsson, Frank & Weeda, P.C.
1400 Sixteenth Street, N.W.
Suite 400
Washington, DC 20036-2220

Dear Mr. Weeda:

Your petition submitted on behalf of the Association of Independent Blood Centers, Inc., requesting the Food and Drug Administration to recognize, and so inform industry, that computer software developed by blood centers for their own use is not subject to the device premarket notification requirements was received by this office on 01/28/97. It was assigned docket number 97P-0039/CP 1 and it was filed on 01/28/97. 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
Dockets Management Branch

ACK1