DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 1997

Ms. Anna J. Baldwin
Director, Technology and Regulatory Affairs
HIMA
1200 G Street, N.W., Suite 400
Washington, D.C. 20005

Dear Ms. Baldwin:

As you are aware, we have received two citizen petitions (docket numbers 97P-0315/CP 1 and 97P-0315/CP 2). These petitions request that the agency maintain its "policy" of requiring at least two years worth of clinical data prior to filing of a premarket approval (PMA) application for spinal implant devices and that approval be refused for any applications without a substantial amount of this type of data.

A general discussion of the minimum acceptable length of patient follow-up for marketing approval of spinal implant devices will be held on December 11, 1997 at the next Orthopaedic and Rehabilitation Devices Advisory Panel (the Panel) meeting. Interested members of your organization may wish to comment during the scheduled open public session of this meeting. Due to time constraints, the number of commentors will not be large and the time allowed to speak will be kept short. If necessary, this and similar topics may be discussed in more depth at a future Panel meeting.

Interested members should be instructed to contact Ms. Jodi Nashman at 301-594-2036 before December 3, 1997, to request time to speak during the open public session at the next Panel meeting.

If you have any other questions or concerns, please feel free to contact Mr. Mark Melkerson, Branch Chief of the Orthopaedic Devices Branch, at 301-594-2036.

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Center for Devices and
Radiological Health

cc: Orthopedic Manufacturers