

**G. KARLIN MICHELSON, M.D.**

A PROFESSIONAL CORPORATION

*Diplomate American Board of Orthopaedic Surgery*

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Document Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

12/15/99

re: Docket No. 97N-484S

Dear Sirs:

I have been an Orthopedic Spinal Surgeon since 1980. I have used allograft bone extensively in my practice saving many thousands of patients the pain, disability, and risk of complications associated with the harvesting of autologous grafts.

I am the inventor of the metal spinal cage technology now offered for sale in this country by Medtronic Sofamor Danek, Sulzer-Medica Spine-Tech, and Surgical Dynamics Inc. Despite that my strong preference in that regard has been to implant the threaded cortical bone dowels made available through Medtronic Sofamor Danek. In my hands this has proven itself to be an excellent product; performing well at surgery, and resulting in a very high rate of fusion, without any graft related problems for the patients. Similarly, I have also used various allograft cortical bone grafts made available through other distributors; with the same excellent results.

The availability of these allograft cortical bone grafts is essential to my practice, and to the welfare of my patients. I have had no problems, nor am I aware of any problems that would warrant the regulation of these cortical allografts as medical devices.

Sincerely yours,



97N 484S

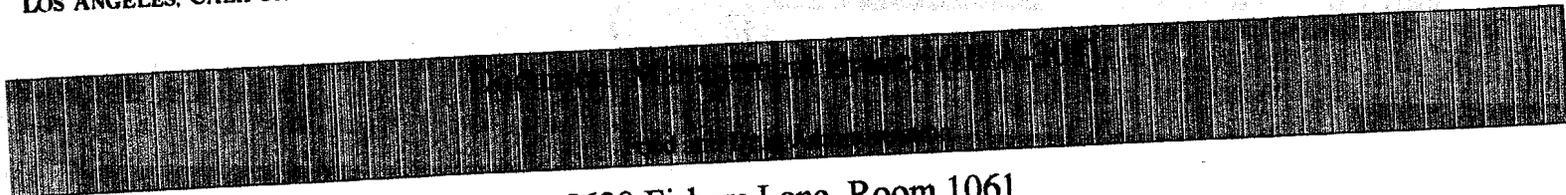
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