



Arthroscopic Surgery
foot & Ankle Surgery
Fracture Surgery
Hand Surgery
Joint Replacement
Spinal Disorders/Surgery
Sports Medicine Injuries

December 13, 1999

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HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
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RE: Docket #97N-484S

Dear Sirs:

I am sending this letter which is to become part of the public comments with regard to the FDA's proposed regulation of bone allograft tissue which was initially published in the September 30, 1999 issue of the Federal Register.

I am a spine surgeon with extensive experience in both the surgical aspects and product development areas of spinal implant.

It is my strong opinion that the FDA need not and should not regulate allograft material itself since adequate regulations already are in place for bone banks.

On the other hand, if the allograft material is machined or formed into an implant or a device, I think these machined or molded commercial products ought to undergo the same degree of device regulation as is required for metallic or implants of other materials. The suggestion given above would be a simple method of determining whether or not allograft tissue is used generically or as a "device" with specific dimensions, angles, thickness and physical characteristics.

Thank you for including my opinions in this debate.

Sincerely,

Stephen D. Kuslich, M.D.

Spine Surgeon

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