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

Docket Number 97N-484S

To Whom It May Concern:

I write concerning the proposed FDA regulation to allow FDA control of allograft bone material as medical devices. As a spinal surgeon who depends on a reliable source of allograft tissue for spinal reconstructive surgery I am concerned that this proposed change in regulation would have a significant detrimental effect on patient care. There are many times when allograft tissue is the only material suitable for spinal reconstruction and stabilization. If this tissue was required to go through the same approval process as medical devices, I believe it would result in a significant shortage of available material. This is due to the fact that allograft tissue is provided for the most part by nonprofit tissue banks who do not have the resources to jump through the regulatory hoops that are imposed on new medical devices. Additionally, as the basic material for this "device" is human bone tissue which has inherent differences from donor to donor, it would seem to be impossible for these "devices" to achieve a uniformity of properties that is required for devices. Physicians are well aware of the limitations inherent in allograft tissue and do not need additional oversight from the Food and Drug Administration. For the sake of quality patient care I ask that you do not proceed with a change in classification of allograft materials used in surgery to medical devices.

Thank you in advance for your thoughtful consideration.

Warmest Regards,

Joe T. Minchew, MD
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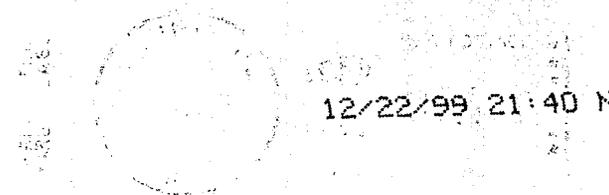
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