

**COASTAL NEUROSURGICAL ASSOCIATES AND SPINE CENTER, P.A.**

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Food and Drug Administration  
5630 Fishers Lane Room 1061  
Rockville, MD 20852

To Whom It May Concern:

This letter is in reference to docket number 97N-484S. It has come to my attention that the FDA is considering regulating Allograft bone as a medical device. As neurosurgeons we use Allograft on a regular basis. We have done so for years without significant difficulties. I think that there have been high standards in terms of quality of this bone and very few problems have occurred with it. I would ask that you do not change the regulation of this device. At this time it is difficult enough to get the proper Allograft bone for surgical cases. I am afraid that any change in this regulation would further delay obtaining the bone and ultimately **harm patients.**

Again we have used Allograft bone for many many years without difficulties. I do not see a reason why this should be changed. Certainly it would not be to the advantage of our patients.

Sincerely,



Adam P. Brown, MD

APB/deh

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