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Document Branch (HFA-305) Food and Drug Administration
5630 Fishers Lane, Room 1061
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Gentlemen:

This letter is written in reference to Docket #97N-484S. By way of introduction, I am a Board certified, fellowship-trained spinal surgeon with many years experience in the field. It has been brought to my attention that issues have been raised regarding the advisability of regulations applied to allograft material used for the purposes of interbody fusion. It's my further understanding that these issues have been raised by members of the Spine Tech Corporation seeking to get F.D.A. action to regulate this material. In my view this is a blatant, business-driven attempt by a company that has seen erosion of its market share for its interbody fusion device as the result of a number of specialists employing allograft rather than their titanium cage.

In my view, patients should be afforded the opportunity to benefit from the availability of allograft used as an interbody spacer, as well as the metallic devices on the market. Indeed, allograft material has a far longer safety track record than any of the present metallic devices on the market. It is not in the public's best interest to tie spine specialists' hands by acceding to the requests made by various business entities whose motives are transparent.

Sincerely,

Daniel J. Sullivan, M.D.

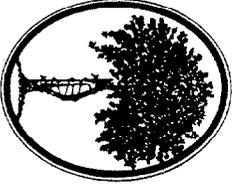
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cc: Ron Pickard
Sofamor Danek

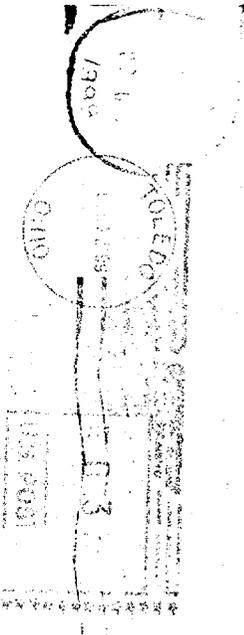
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