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

Re: **DOCKET #97N-484S**

To Whom It May Concern:

I have recently become aware of proposed changes regarding the regulation of some types of allograft as medical devices. I am greatly concerned about this proposal, given the fact that bone banks do not have the resources, nor the expertise, to satisfy the FDA's lengthy premarket requirements. I believe that this could result in a shortage of bone products which are used quite commonly in neurosurgical practices. Although I think the FDA should continue regulating bone as tissue, I am against the newly-mentioned proposal.

Sincerely,

Timothy K. Putty, M.D.

TKP/pck/bw

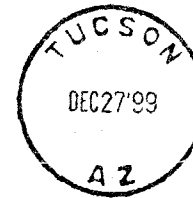
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