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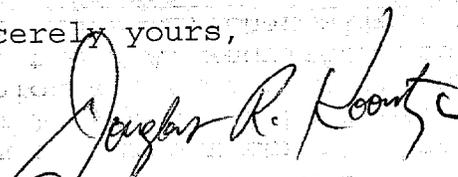
RE: Docket # 97N-484S

To Whom It May Concern:

I am a neurosurgeon who has been in practice for a little over 12 years. I have been using banked bone in some fashion all that time and have been very happy with the way you, the FDA, regulates its safety. I absolutely do not feel, however, that allograft bone tissue should be regulated differently now than it has been in the past. In other words, I feel that it is not a medical device and therefore should not have those types of regulations placed on it. Again, I feel that the safety of banked bone is incredibly important and indeed that has been done well through the years. In fact, I believe the bone that is available for fusion purposes is safer now than it has ever been.

In closing, I feel that you are doing a very good job with allograft bone tissue for fusion purposes. I do not, however, feel that this bone is a medical device and should not be treated as such.

Sincerely yours,



Douglas R. Koontz, M.D.

DRK:djl

dr: 12/11/99/TSI39917

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