THE BOSTON SPINE GROUP, LLC

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January 18, 2000

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

Re: Docket Number 97N-484S

Dear Sirs:

I would like to comment on the proposal to regulate allograft bone tissue. I am an orthopedic spine surgeon and have been in practice for nearly eight years. I use allograft bone products on a regular basis and have found them to be safe and have predictable results. In my practice with complex spinal reconstructive procedures, I find that bone is one of the best choices to help create spinal fusions. There are many different products available and we use all of them on a regular basis. This includes demineralized bone matrix, bone dowels, femoral ring allografts and other more generic tri-cortical bone grafts. Each has a specific indication for which it works well. Bone has been used in orthopedic surgery for decades without regulation and as far as I know without significant problem.

I would not like to see the supply of these bone products limited, so I would respectfully ask that any consideration for regulatory action be carefully considered.

Respectfully,

Scott G. Tromanhauser, M.D.

SGT/pj

Affiliated Services

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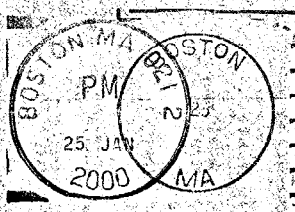

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