

BOSTON ARTHRITIS & SPINAL SURGERY

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Document Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane – Room 1061
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To Whom It May Concern:

In reference to Docket #97N-484S, which is a proposal to regulate allograft tissue as a medical device.

This is very redundant at best as tissues are presently provided by approved FDA-regulated bone banks. As it stands today, there is already a limited amount of allograft material available for reconstructive orthopedic surgery. Further regulation would only result in restriction of this available resource.

Providing that the Food & Drug Administration continues to oversee the integrity and safety of these suppliers, I fail to see any further benefit to the patient in terms of safety and efficacy.

I would be happy to answer any further questions you might have in this regard.

Very truly yours,

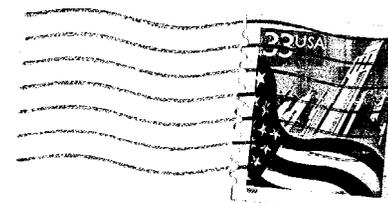
Michael D. Mason, D.O.
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