Salem Spine
And Scoliosis
Center

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December 17, 1999

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

Dear Sirs:

I am writing a letter regarding regulation of allograft tissue (docket #97N-484S). The use of biological materials is greatly helpful in orthopaedic spine surgery. It can at times limit the need for other implanted devices such as pedicle screws. I have been using threaded cortical bone dowels to promote healing in lumbar fusion surgery. I have been pleased with their efficacy and safety. I would urge you not to regulate this as a medical device.

Sincerely,

Harlan B. Daubert, M.D.
HBD/bma

97N 484S

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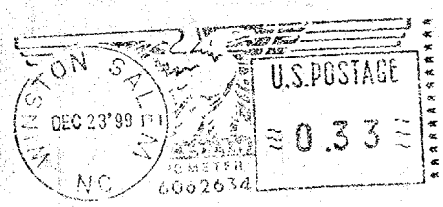

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