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

RE: Docket No. 97N-484S

To Whom It May Concern:

As a surgeon who has used allograft bone implants in both the cervical and lumbar spine successfully for many years, I think this is definitely a tissue. Even though it has been shaped by mechanical means, this does not alter the fact that it is tissue.

I think FDA regulation of this as a device would certainly harm the everyday practice of medicine and would jeopardize the availability of this tissue for use in the spine and thus jeopardizing the patients who rely on it for use.

Therefore, I strongly object to the Regulation Docket #97N-484S.

Sincerely,

Jon T. Ledlie, M.D.

JTL/jc

"A Tradition of Excellence in Neurosurgical Care"

97N 484S

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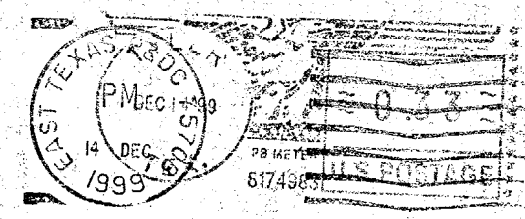

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