

EMORY HEALTHCARE
THE EMORY CLINIC, INC.

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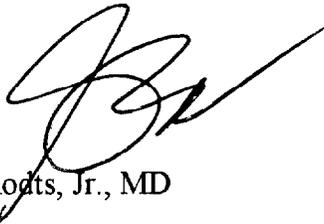
March 3, 2000

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
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Gentleman:

I received a copy directly from Dr. John Brannigan regarding his opinion on the use of allograft bone and the need for FDA device regulation. Though he is published on the subject, I tend to differ with his opinion. Unlike Dr. Brannigan, I personally have no financial stake in the sale of any type of bone allograft implant. We have been using allograft bone in the cervical and lumbar spine for over a decade. Whether it is in the form of a femoral ring, fibular strut, allograft machine bone dowel, or wedge, we have found these bone grafts to perform superbly in both the mechanical sense and in terms of biological incorporation. In difference to Dr. Brannigan's opinion, we have found the compression strength of allograft to be extremely predictable and sufficient in all cases when used within the standard of acceptable neurosurgical and spinal care. We all are aware of the enormous marketing and financial implications of this argument, but the plain and simple fact remains that allograft has been used for many years and has functioned extremely well in multiple areas of the body, including the spine.

Sincerely,



Gerald E. Rodts, Jr., MD

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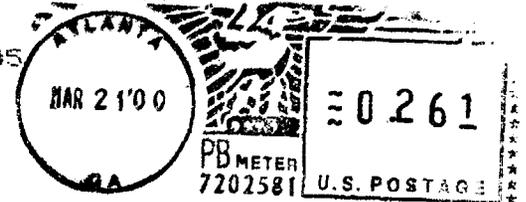
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