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April 9, 2007

Division of Dockets Management
Food and Drug Administration
5630 Fishers lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2005P-0121

Dear Sir,

In June 2006 I had the opportunity to testify before the Orthopaedic and Rehabilitation Devices Panel hearing on whether to retain non-invasive bone growth stimulators as Class III devices. At that time I strongly supported the retention of non-invasive bone growth stimulators, along with every other M.D. panel member, as Class III devices. I continue to strongly support the decision of the Panel to maintain non-invasive bone growth stimulators as Class III devices.

I have used non-invasive bone growth stimulators on a routine basis in my surgical practice for almost 20 years. They continue to be a highly dependable and cost-effective adjunct particularly in patients undergoing spinal fusion with any number of risk factors for developing a non-union

What was particularly disturbing about the petition to down-classify these devices to Class II was the cavalier assumption that any of the existing devices could be considered predicate devices for future devices despite some changes in product design. It became clear throughout the day long testimony in June that this was, and is, simply not valid from a scientific approach. Even though these devices are non-invasive and provide no direct harm to the patient, the real harm comes from their inefficiency. Small changes in product design and signal can and do result in devices which are ineffective compared to existing, well-tested devices. Therefore, the use of ineffective devices introduced into the marketplace would result in patients with difficult to heal fusions developing pseudoarthroses and the concomitant cost of human suffering and the added financial burden of pseudoarthrosis repair. Simply put, down classification and the resultant introduction of ineffective medical devices would be a clinical and cost-effectiveness disaster.

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Thank you for the opportunity to testify before the Panel in June and I congratulate the Panel for making the appropriate decision to maintain non-invasive bone growth stimulators as Class III devices so that patients will continue to be afforded reliable, safe and most importantly, effective medical devices.

Yours truly,

Neil Kahanovitz, M.D.