



Texas Back Institute

August 10, 2005

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Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

RE: FDA Docket 2005P-0121/CCP1;
Letter in Opposition to the Reclassification of Non-Invasive Bone Growth Stimulators

Dear Sir or Madam:

The purpose of this letter is to register my opposition to the reclassification of external bone growth stimulators from Class III to Class II. It is my opinion that such a classification, requiring only "special controls" would fail to ensure the safety and effectiveness of bone growth stimulation devices, and would contribute the degradation of this promising technology.

In my 20 years in private practice as a spine surgeon, in New England region now in Dallas, Texas, and as a proponent of external stimulation (particularly PEMF), I feel compelled to express my opinion on this matter. When introducing energy into the body, it is very important to know that the device has been thoroughly tested and has been clinically proven safe and effective. As a clinician, I have felt confident in prescribing the commercially available PEMF devices because of the clinical results obtained from well-controlled studies. Further, I am aware of the rigorous controls imposed on manufacturers of Class III devices, and feel they are necessary to ensure a safe and reliable device.

Bone growth stimulation research is on going, but there is still much that we do not understand about the effects at the cellular level. We do know that different technologies, signals and intensities can produce very different effects. These varied effects and a lack of full understanding of the various mechanisms of action, clearly indicate that this technology is NOT generic and should not be regulated as such. I urge you to deny RS Medical's petition for the down-classification of BGS devices.

Sincerely,

Barton L. Sachs, M.D., MBA
President-TBI Research Foundation
Active Staff Faculty and Practicing Surgeon
Texas Back Institute

2005P-0121

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