





THE ORTHOPEDIC CLINIC ASSOCIATION, P.C.

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August 24, 2005

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

Re: FDA Docket 2005P-0121/CCP1;
Request to Deny Reclassification of External Bone Growth Stimulators

Dear Sir or Madam:

I write to oppose the RS Medical petition for the reclassification of external bone growth stimulator ("BGS") devices for Class III to Class II and to request that the Food and Drug Administration ("FDA") deny this petition. I have been practicing orthopedic surgery for almost thirty years. I am currently practicing in The Orthopedic Clinic in Phoenix Arizona. As a part of my regular clinical practice, I treat patients with complex problematic fractures, including treatment of nonunions and spinal fusions. I have also augmented my clinical practice over the years with research specifically focused on evaluating noninvasive electromagnetic and combined magnetic field bone simulation for nonunions. I have attached a copy of my curriculum vitae to this statement. Based upon my clinical and research experience, I oppose the reclassification of BGS devices because I believe that a down classification may negatively impact the clinical outcomes for individual patients who are prescribed BGS devices.

I have extensive experience with the use of pulsed electromagnetic fields (PEMF), ultrasound, combined magnetic field ("CMF"), and capacitive coupling BGS devices and prescribe these devices regularly for patients in my clinical practice. Based upon my clinical and research experience with these devices, I believe the currently marketed PMA approved devices are effective in assisting physicians as they treat a variety of problem fracture, including non-unions. Unlike many other orthopedic devices which are designed to assist or facilitate a patient in his/her daily activities, BGS devices are curative and are used to heal nonunion factures. As a result, physicians can prescribe BGS devices as effective alternatives to surgery for treatment of nonunions. Relying on a less effective device can

1 William Carroll, Vice President, Research and Development, RS Medical, Reclassification Petition for the Non-invasive Bone Growth Stimulator under Section 513(e) of the FDCA, Docket 2005-0121/CCP 1 (file Feb.9, 2005) ["RS Medical Petition"].

have detrimental results to a patient's treatment. Specifically, as the healing time is delayed for a nonunion, the probability of clinical success decreases. For the patient, failed efficacy of a BGS device can result in (i) severe impairment in the affected extremity (ii) surgery or repeated surgery and (iii) in severe cases, amputation of the extremity. In other words, a BGS device's failure, as defined by a decrease in efficacy, can result in significant negative clinical outcomes for patients.

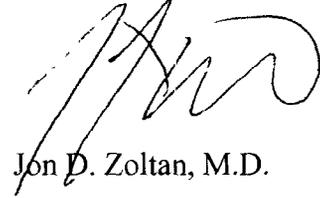
Clinical data demonstrate that the currently marketed FDA-approved BGS devices are safe and effective for treating nonunions and spinal fusions. However, the literature in this area and my own research experience indicate the mechanism of action for these devices is largely unknown. Laboratory and animal data demonstrate electrical and electromagnetic fields can influence biologic processes, such as bone growth at the cellular level. The literature demonstrates even slight modifications of a signal in BGS devices can result in different cellular effects. Such variations can lead to potentially significant decreases in the BGS device's efficacy, as well as potentially unanticipated adverse effects on other biologic processes. It is therefore essential that the safety and efficacy of each device be demonstrated through rigorous preclinical and clinical data.

New BGS devices must be subject to the same preclinical and clinical testing requirements as the currently available BGS devices before being approved for marketing. Manufacturers must be required to demonstrate to the FDA's satisfaction that their proposed BGS device is safe and effective for treating nonunions or spinal fusions. Merely establishing that they are "substantially equivalent" to currently approved BGS technology is not sufficient to establish a particular device's safety and effectiveness. This is essential from a clinical perspective because (i) data suggest that even slight modifications in a device may result in a less efficacious device, (ii) physicians will not necessarily have access to data supporting the safety and efficacy of the actual device he or she is considering prescribing, and (iii) some physicians will erroneously believe that the safety and efficacy of BGS devices marketed through the less-rigorous 510(k) process have been satisfactorily demonstrated through preclinical and clinical trials. Given these risks of a significantly less efficacious product entering the market with perceived FDA approval and the potential for negative clinical outcomes because of a less efficacious device, I believe the safeguards of the Class III regulatory paradigm for BGS devices are necessary for protecting patients.

It is my professional opinion the petition does not propose safeguards sufficient to ensure the clinical safety and efficacy of BGS devices as Class II devices. Further, it is my professional opinion a BGS device with less

efficacy will have detrimental and potentially negative effects on patients. I therefore oppose the reclassification of BGS devices to Class II and request the FDA continue to regulate BGS devices as Class III devices.

Respectfully,

A handwritten signature in black ink, appearing to read "Jon D. Zoltan". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Jon D. Zoltan, M.D.