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

Subject: FDA Docket 2005P-0121/CCP 1
Comments in Opposition to the Reclassification of Non-Invasive Bone Growth Stimulators

To whom it may concern:

I am writing to convey my opposition to the reclassification of external bone growth stimulators from Class III to Class II. My opposition to such a "down-classification" is based on my research experience.

The mechanism of action of bone growth stimulator technologies is a research subject that is gaining momentum at various universities and research facilities. Published research has shown that variations in the device's output can produce varying results including no clinical or preclinical benefit at all. I have conducted research on two PEMF signals to study the effect of BMP2 and PEMF on rat osteoblastic cell proliferation and gene expression. The results with one PEMF signal and BMP2 demonstrated increased cell proliferation, but the second PEMF signal showed statistically different results. This research indicates to me that different signals produce different results. Further, I am intrigued about the possibility of PEMFs when used to complement BMP2 for a combination treatment.

The action of down-classifying this technology implies it is well understood and may be generically categorized. My research experience supports a different conclusion. The bone growth stimulator technologies are not a generic sort, but are very different and have different cellular effects. The safety and effectiveness of these devices must be proven with preclinical research and well controlled, statistically valid clinical studies.

I am enthusiastic about future, potential clinical applications of appropriately studied PEMF signals. And, I hope that the FDA will consider carefully this request for down-classification of external bone growth stimulation. PEMF poses some intriguing

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opportunities if given the appropriate level of research and control. I urge you to maintain the Class III standards for these technologies.

Sincerely,

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