

April 17, 2007

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;
FDA Federal Register Notice on Panel Recommendation Against the Proposed
Reclassification of Bone Growth Stimulator (“BGS”) Devices**

Dear Sir or Madam:

On behalf of the bone growth stimulator (“BGS”) Reclassification Opposition Group (“BGS Group”), we submit this letter in response to the agency’s request for comments on the Panel recommendation against the proposed reclassification of external BGS devices from Class III to Class II. The BGS Group is comprised of the leaders in this device field—dj Orthopedics, Inc., EBI, L.P., and Orthofix Inc. Collectively, we represent over 50 years of experience with BGS devices and are responsible for 100% of the electrical/electromagnetic external BGS market.

The BGS Group has been actively opposing the petition for reclassification of BGS devices from the time the petition was first filed. We filed comments in response to RS Medical’s original petition and the subsequent amendment outlining the deficiencies. The BGS Group also presented its position at the June 2, 2006 Advisory Committee (“Panel”) meeting which discussed the reclassification petition. RS Medical’s petition failed to meet the statutory requirement for reclassification. We further believe that the legal and regulatory deficiencies of that petition and those noted by the Panel cannot, and could not, be addressed even in a future petition requesting reclassification of BGS devices. As such, BGS devices must remain Class III devices.

2005P-0121

C19

April 17, 2007
BGS Docket
Page 2

On April 2, 2007 RS Medical withdrew its petition. In light of the withdrawal we understand that the agency will terminate the BGS reclassification proceedings. Therefore, the BGS Group will not be filing further comments at this time.

Sincerely,

A handwritten signature in black ink that reads "Edward M Basile". The signature is written in a cursive style with a large initial "E".

Edward M. Basile