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May 12, 2006

BY MAIL

Mark Melkerson
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation (DGRND)
9200 Corporate Boulevard (HFZ-410)
Rockville, Maryland 20850

Re: Questions for the Orthopaedic and Rehabilitation Devices Panel Regarding the Proposed Reclassification of External Bone Growth Stimulator ("BGS") Devices

Dear Mr. Melkerson:

As you know, King & Spalding represents the BGS Reclassification Opposition Group ("BGS Group"), which was formed to address concerns that the proposed Class II regulatory requirements would be inadequate to assure the safety and effectiveness of new BGS devices. The BGS Group is comprised of the leading manufacturers in this device field—dj Orthopedics, Inc., EBI, L.P., and Orthofix Inc.

Through two meetings with members of CDRH and several written submissions, the BGS Group has urged FDA to refuse Panel review and deny the proposed down-classification of BGS devices from Class III to Class II because the reclassification petitioner has failed the following scientific and legal requirements:

- To define the technical specifications and tolerances for BGS devices;
- To define a "generic type" of BGS device for reclassification;
- To propose adequate special controls that would reasonably assure the safety and effectiveness of BGS devices; and
- To present sufficient "valid scientific evidence" demonstrating that the current Class III requirements are unnecessary and that the proposed special controls are adequate.

The Orthopaedic and Rehabilitation Devices Panel will consider the proposed reclassification of BGS devices at the June 2, 2006 meeting. It is critical that the Panel's deliberations and ultimate recommendation reflect the scientific and legal standards mandated

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Mark Melkerson

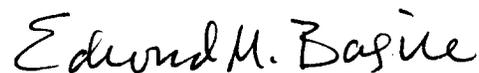
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for reclassification proceedings, as described above. To this end, the BGS Group submits the enclosed questions for the Panel's consideration. These questions cover the regulatory requirements for reclassification and the central characteristics of the BGS technologies. We believe that these questions are essential to ensure that the Panel bases its recommendations on the scientific and regulatory standards imposed by the Federal Food, Drug, and Cosmetic Act.

We look forward to the Panel meeting next month. Please do not hesitate to contact us with any questions.

Sincerely,



Edward M. Basile

Enclosure

cc: Dan Schultz
Donna Bea Tillman
Miriam Provost
Janet Scudiero