Spine Specialists of Boston

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Food and Drug Administration
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Re: FDA Medical Devices Advisory Committee Panel Meeting on Reclassification of Noninvasive Bone Growth Stimulators

Dear Mr. Garcia,

I am writing regarding the September 8, 2020 meeting of the Medical Devices Advisory Committee, Orthopaedics and Rehabilitative Devices Panel. My comment concerns the Panel's consideration of potential reclassification of noninvasive bone growth stimulators (BGS devices) from Class III to Class II. I strongly urge FDA to maintain Class III classification for these devices.

I am an orthopedic surgeon specializing in the spine and have been performing highly complicated spinal procedures for over 20 years. I was able to collaborate on of the early research into the use of bone growth stimulators following spinal fusions. Due to the positive effects the clinical evidence has consistently shown, BGS is a critical aspect of my protocol for post-operative recovery of my patients who meet the criteria to warrant such use. My office works very closely with medical device professionals, many with healthcare backgrounds, who follow the FDA regulations to ensure proper and safe introduction of the BGS to my patients. As a treating physician, it is vital to me to know that any BGS device I prescribe will have been proven to be safe and effective through robust clinical studies and application of FDA's most stringent, Class III regulatory controls. The clinical consequences of ineffective or unsafe BGS devices are far too great to support anything less than FDA's highest level of regulation.

Many patients who undergo spinal fusion surgery have health factors or comorbidities that make them at risk for a failed spinal fusion or pseudarthrosis. For these patients, BGS devices are of critical clinical importance for a successful spinal fusion following surgery. The risk of a device that is not efficacious is simply unacceptable. For example, pseudarthrosis results in chronic medical conditions with debilitating, lasting adverse effects on not only patients' physical health, but also their mental health and quality of life. Consistent with my experience, the clinical literature documents that the adversity experienced by patients

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with pseudarthrosis in these regards is comparable to that of patients with end-stage hip arthrosis and worse than that of patients suffering congestive heart failure.

BGS are high-stakes devices. Patients and clinicians thus deserve and need to have the greatest assurance of their effectiveness and safety. BGS devices encompass a range of distinct technologies, waveform parameters, functionalities, designs, dosimetries, and intended uses. Given the nature of and dissimilarities among BGS devices, a single set of special controls could not reasonably assure the safety and effectiveness of each distinct type of BGS device. Even minor changes to BGS devices may profoundly impact their safety and effectiveness in unknown ways that render Class III controls, such as rigorous clinical studies and pre-approval manufacturing review, necessary. While Class II standards such as "substantial equivalence" of technological characteristics are appropriate for many devices, because of the complexities and uniqueness of BGS waveforms, these devices do not lend themselves to proof of effectiveness and safety merely by the appearance of similar technical characteristics. Instead, device-specific data, including clinical data, and the strictest levels of FDA review are the only mechanisms sufficient to ensure that BGS devices will, in fact, perform as intended. BGS devices should therefore continue to be regulated in Class III.

I appreciate FDA's thoughtful consideration of this comment.

Sincerely,

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