August 15, 2020

Via E-Mail to Patricio.Garcia@fda.hhs.gov with copy to James.Swink@fda.hhs.gov and Randoshia.Miller@fda.hhs.gov

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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 upcoming 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 a practicing neurosurgeon with an emphasis in minimally invasive spine surgery. As the population of patient's requiring spinal surgery has aged; we have seen an increasing need for multilevel arthrodesis in conjunction with an increasing number or patient comorbid conditions such as diabetes and cancer. Achieving solid bony fusion in this growing but high-risk population has become more challenging and bone growth stimulators have played a key role in my care of these 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 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. In short, patients with a nonunion, particular a multilevel nonunion rapid lose their ability to walk due to rippling back pain.

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 the FDA's thoughtful consideration of this comment.

Sincerely,

Joshua M. Ammerman, MD

cc: James Swink (James.Swink@fda.hhs.gov)
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