Orthopedics
UNIVERSITY OF COLORADO

August 26, 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 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 the Chair of Orthopedics at the University of Colorado and has been a spine surgeon for 23 years. There is great value to these Bone stimulators for our complex, spine patients with osteoporosis and complex reconstruction. I have used them with great success over the past 16 years. As the 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. Our Department here in Colorado has participated in these post market analysis of the devices and the results were excellent. 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 pseud arthrosis. 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, pseud arthrosis 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 pseud arthrosis 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, dosimetrist, 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.

Our patient will also pay out of pocket for these devices as they are desperate to get the best treatment. If the device market is not controlled anymore it will be impossible to reassure the patients of the value of the device.

I appreciate FDA's thoughtful consideration of this comment.

Sincerely,

Evalina Burger, MD
Professor and Chair Department of Orthopedics
University of Colorado SOM

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