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Center for Devices and Radiological Health
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:

Hello, my name is Peter Whang and I am an Associate Professor in the Department of Orthopaedics and Rehabilitaiton at the Yale University School of Medicine. I am writing to you regarding the meeting of the Medical Devices Advisory Committee, Orthopaedics and Rehabilitative Devices Panel that is scheduled to take place on September 8, 2020. I would like to take this occasion to share my concerns about the possibility that the Panel could potentially reclassify noninvasive bone growth stimulators (i.e. BGS devices) from Class III to Class II. In short, I strongly urge the FDA to maintain the Class III designation of these devices.

As an orthopaedic spine surgeon who routinely performs complex fusion procedures, I can tell you from experience that nonunion is a potentially devastating complication of these operations which may give rise to significant clinical morbidity (e.g. pain, neurologic symptoms), functional

disability, and compromised quality of life. Many of my patients who undergo spinal fusion surgery have one or more medical comorbidities or other risk factors for suboptimal bone healing such as osteoporosis, tobacco use, steroid therapy, history of previous surgery with possibly compromised vascularity and soft tissue coverage, and multilevel constructs, which collectively increase their potential for developing a nonunion. Consistent with my own experiences, there is ample literature documenting the detrimental effects of spinal nonunions which have been shown to be comparable to that associated with end-stage hip arthrosis and worse than that experienced by patients with congestive heart failure.

There is ample clinical data confirming the safety and efficacy of BGS devices for promoting bone formation and these devices have previously been approved by the FDA as a noninvasive, adjunctive treatment option for patients undergoing spinal fusion surgery who are at high risk for pseudarthrosis. Because of their potential for increasing arthrodesis rates and improving clinical outcomes, BGS represents a valuable tool for minimizing the incidence of nonunion following spinal fusion surgery and I frequently utilize these devices in my own practice. Thus, it is extremely important for me to have the assurance that any BGS device that I prescribe for my own patients will not only have been proven to be safe and effective based upon the results of robust clinical studies but are also subject to the FDA's most stringent, Class III regulatory controls. For many of my patients, BGS are of critical clinical importance for achieving a successful spinal fusion and the possibility that a device may not be efficacious is simply unacceptable. In my mind, the clinical consequences of ineffective or unsafe devices are far too great to support anything less than FDA's highest level of regulation for BGS. Patients and clinicians alike deserve to have the greatest assurance of the effectiveness and safety of their prescribed BGS treatment.

Current BGS devices encompass a wide range of disparate technologies, waveform parameters, functionalities, designs, dosimetries, and intended applications. Given the disparate nature of these commercially available BGS devices, a single set of specific controls could not reasonably safeguard 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 such that Class III controls including rigorous clinical

studies and pre-approval manufacturing review would become necessary to ensure their optimal clinical performance. While Class II standards such as "substantial equivalence" may be adequate for certain technologies, because of the complexities and individualities 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 high-quality clinical evidence as well as the adherence to the strictest levels of FDA review are the only mechanisms sufficient to ensure that BGS devices will in fact perform as intended and maximize a patient's chances of obtaining a solid spinal fusion. It is no exaggeration to say that the stakes of BGS are incredibly high for which reason I strongly believe that these devices should continue to be regulated according to Class III criteria.

Thank you for the opportunity to share my thoughts about BGS and my experiences using these devices with my own patients. I appreciate the FDA's respectful consideration of my comments and would be happy to provide more input at any time.

Sincerely,

Peter Whang

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