Duke Orthopaedic Surgery

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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 a board certified orthopaedic surgeon in an academic practice at Duke University. I am at a busy level 1 trauma center and tertiary referral center. My partners and I consistently care for the most complex and challenging cases. 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.

For patients with fractures to be treated with BGS devices, these devices are of critical clinical importance. The risk of a device that is not efficacious is simply unacceptable. For example, fracture non-unions are 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 non-unions (e.g., of long bones) in these regards is comparable to that of patients with end-stage hip arthrosis and worse than that of patients suffering congestive heart failure. The frequency of this is greater for patients with common co-morbidities, such as those who are smokers, diabetics or obese. I have overall had an excellent clinical experience with challenging fractures using BGS devices and there is incredible value in there application. We rely on the proper vetting and assurance that the BGS devices that we have available are clinically proven.

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

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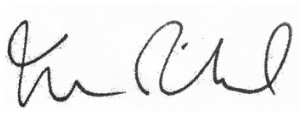
parameters, functionalities, designs, dosimetries, and intended uses. Given the nature of and dissimilarities among BGS devices, a single set of special controls could not reasonably assure the safety and effectiveness of each distinct type of BGS device. Even minor changes to BGS devices may profoundly 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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cc: James Swink (James.Swink@fda.hhs.gov)
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