August 20, 2020

Texas Back Institute

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

Patricio Garcia
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave.
Bldg. 66, Rm. 5216
Silver Spring, MD 20993-0002
Patricio.Garcia@fda.hhs.gov

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 have been practicing orthopedics for nearly 40 years. During my training at the University of Pennsylvania, I worked with Dr. Carl Brighton who was one of the pioneers in electrical stimulation for bone healing. In fact, I did some early experimentation into the effects of induced electrical stimulation with magnetic calls. After being in practice, I was involved in the the AME BGS Spinal Stim Study from 1986-89. So, I am aware of the benefits of BGS for spine fusion healing. 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.

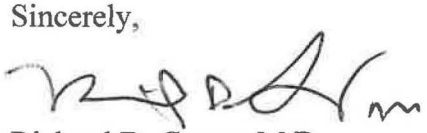
Many patients who undergo spinal fusion surgery have health factors or comorbidities that make them at risk for a failed spinal fusion or pseudarthrosis. For these patients, BGS devices are of critical clinical importance for a successful spinal fusion following surgery. The risk of a device that is 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 problems experienced by patients with pseudarthrosis are comparable to that of patients with end-stage hip arthrosis and worse than that of patients suffering congestive heart failure. Each revision surgery for pseudarthrosis makes it more difficult to achieve a solid fusion. My philosophy is to do the best surgery that one can do the first time and to increase the patient's chance of a successful fusion especially for those who have comorbidities and are at high risk for pseudarthrosis.

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,



Richard D. Guyer, M.D.
Chairman, Texas Back Institute Research Foundation
Co-Founder, Texas Back Institute
Past President, North American Spine Society

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