8/17/2020

***Via E-Mail to Patricio.Garcia@fda.hhs.gov***

Patricio Garcia
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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 an active Neurosurgeon who performs over 500 spinal operations each year. Many of these operations are performed on patients over age 50 and include arthrodesis. I maintain conservative and judicious indications to fusion but appreciate having the ability to utilize BGS to augment arthrodesis with confidence of effectiveness and safety.

I have used BGS for over 30 years, both internal and external. The devices all have distinct technologies, waveform parameters, functionalities, designs, dosimetries, and intended uses. A single set of special controls could not reasonably assure the safety and effectiveness of each distinct type of BGS device. I do not believe that Class II standards such as "substantial equivalence" of technological characteristics are appropriate for these wide-ranging technologies. Device-specific data, including clinical data, and the strictest levels of FDA review are the only mechanisms sufficient to ensure that BGS devices will function as expected.

Thank you for your attention in this matter.

Sincerely,
William C. Welch, MD, FACS, FAANS, FICS, FAANOS

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