MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION
Innovation Today for Better Health Care Tomorrow™

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RE: Potential reclassification of Non-invasive Bone Growth Stimulator Devices (product codes LOF and LPQ)

Dear Mr. Garcia:

On behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing innovative and entrepreneurial medical technology companies, I am providing the following comments regarding the upcoming meeting of FDA's Medical Devices Advisory Committee, Orthopaedic and Rehabilitative Devices Panel (Panel) to consider the potential reclassification of non-invasive bone growth stimulators (product code LOF) and ultrasound muscle stimulators for uses other than applying therapeutic heat (product code LPQ) (collectively, BGS devices). MDMA represents hundreds of medical device companies, and our mission is to ensure that patients can access the latest advancements in medical technology.

BGS devices, also known as osteogenic stimulation devices, are a non-invasive, clinically efficacious, and cost-effective treatment for important indications including non-union fractures, fresh fractures, and adjunctive treatment to spinal fusion surgery. BGS devices were first approved by FDA in 1979, and since that time, have been classified into Class III/PMA, which requires these devices to be proven to be safe and effective through robust clinical studies and application of FDA's most stringent regulatory controls.

BGS devices consist of a broad range of technological characteristics including different waveform parameters, functionalities, designs, dosimetries, and intended uses. As a result of these unique elements among BGS devices, MDMA believes that maintaining the Class III designation is appropriate.

FDA has proposed to require "clinical performance data" in non-invasive BGS devices as a Class II special control to support downclassification.[1] However, FDA also proposes to "allow for flexibility in study design and the level of clinical evidence needed" to enable BGS

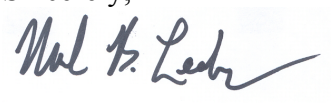
[1] FDA, Physical Medicine Devices; Reclassification of Non-Invasive Bone Growth Stimulators; Proposed amendment; proposed order; request for comments, 85 Fed. Reg. 49986, 49992 (Aug. 17, 2020)

marketing authorization.[2] The unknowns that FDA has previously acknowledged about BGS technology (e.g., unknowns about how waveform parameters impact clinical response and unknowns about how BGS device modifications affect clinical performance) necessitate substantiation of each new BGS device by the highest-level clinical data (Level 1 and 2 evidence), similar to the randomized, controlled clinical trials that have been required to date to support BGS PMA approval.

The Class III framework is also key to clinical research and technological innovation of BGS devices. BGS manufacturers are consistently evaluating optimizing device use for current indications as well as addressing new indications to meet patient needs, seeking to meet the statutory criteria for PMA approval.

MDMA appreciates this opportunity to comment on FDA's consideration of the potential reclassification of BGS devices. As FDA acknowledged following the last Panel review of BGS Devices, these devices are appropriately regulated in Class III and do not meet the statutory criteria for Class II reclassification. MDMA strongly encourages the Panel to again recommend that BGS devices should remain in Class III.

Sincerely,



Mark Leahey

cc: James Swink (James.Swink@fda.hhs.gov)
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[2] Id. at 49990.