



July 18, 2020

Ernest C. Chisena, M.D., M.S.  
Orthopedic Attending Surgeon



Jahangir S. Rastegar, Ph.D.  
Associate Professor  
Mechanical Engineering Department Stony Brook University  
Stony Brook, NY 11794-2300

Sent via email to: [echisenamd@gmail.com](mailto:echisenamd@gmail.com)

Re: Citizen Petition – Docket Number FDA-2020-P-0945

Dear Dr. Chisena and Dr. Rastegar:

This is an interim response to the petition filed with the Food and Drug Administration (FDA) on February 25, 2020. In the petition, you requested FDA force Exogen-Bioventus to prove that ultrasound is responsible for enhancing fracture healing, as claimed in their premarket approval application. Specifically, you indicate the effectiveness of Exogen Ultrasound Bone Healing System to enhance bone healing should be revisited because it is important for the appropriate treatment of patients that consideration be given to the alternative explanation that increased soft tissue pressure over the fracture caused the enhancement.

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen's petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Karen Fikes of our Office of Policy Staff at (301) 796-9603.

Sincerely,

Ellen J. Flannery, JD  
Deputy Center Director for Policy  
Director, Office of Policy  
Center for Devices and  
Radiological Health