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April 16, 2007

**VIA FEDERAL EXPRESS AND
HTTP://WWW.FDA.GOV/DOCKETS/ECOMMENTS**

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Orthopedic Devices; Reclassification of Non-Invasive Bone Growth Stimulator
Docket No. 2005P-0121

Dear Sir or Madam:

Smith & Nephew is a global medical technology business, specializing in Orthopedic Reconstruction, Orthopedic Trauma and Clinical Therapies, Endoscopy and Advanced Wound Management products. Smith & Nephew is dedicated to helping improve people's lives. Smith & Nephew manufactures the EXOGEN Bone Healing System, a low-intensity ultrasound fracture healing system for the treatment of certain nonunion and fresh fractures.¹

FDA has considered down-classifying certain electro-magnetic field non-invasive bone-growth stimulators from class III to class II, in response to a citizen's petition. On June 2, 2006, the Orthopedic and Rehabilitation Devices Panel recommended that non-invasive bone growth stimulators (BGS) be retained in class III. In a recent Federal Register notice, FDA has proposed retaining non-invasive bone-growth stimulators in class III.² Smith & Nephew

¹ The EXOGEN 4000+, or any other EXOGEN Bone Healing System, is indicated for the non-invasive treatment of established nonunions excluding skull and vertebra. In addition, they are indicated for accelerating the time to a healed fracture for fresh, closed, posteriorly displaced distal radius fractures and fresh, closed or Grade I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopaedically managed by closed reduction and cast immobilization.

² See 72 Fed. Reg. 1951, 1953 (Jan. 17, 2007).

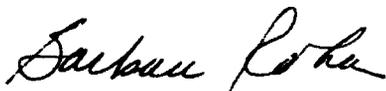
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commends FDA for this decision, and notes that like other non-invasive BGS, ultrasound BGS should remain in class III.

Smith & Nephew again applauds FDA for its decision to retain non-invasive BGS devices in class III, and looks forward to FDA finalizing its proposal.

Sincerely,



Barbara Rohan
Vice President, Government Affairs

BR/gp:b1097

Docket Management Comment Form

Docket: 2005P-0121 - Orthopedic Devices; Reclassification of Non-Invasive Bone Growth Stimulator

Temporary Comment Number: 129193

Submitter: Mrs. Barbara Rohan	Date: 04/16/07
Organization: Smith	
Category: Device Industry	
Issue Areas/Comments	
General See Attachment	
Attachments 2005P-0121-T129193-Attach-1.pdf	

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