

August 4, 2005

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

Re: Docket 2005P-0121/CCP 1

Request for a “Hold” on FDA’s Review of RS Medical’s Petition for Reclassification of the Non-invasive Bone Growth Stimulator (Docket 2005P-0121/CCP 1)

Dear Sir or Madam:

On July 27, 2005, RS Medical received informal comments via e-mail from the Agency resulting from the Agency’s initial review of the above referenced petition. The comments reflect what RS Medical believes to have been a thorough and careful analysis of the petition by the FDA review staff. While some of the comments can be addressed quickly, RS Medical will need additional time to fully address others.

In addition, a number of comments in opposition to the petition have been submitted to Dockets Management in the last few weeks, most notable are those submitted by, or on behalf of, the companies that have approved premarket approval applications (PMAs) for non-invasive bone growth stimulators. While in our opinion these comments for the most part lack any merit, they add to the complexity of the review process, and need to be addressed.

It is RS Medical’s understanding that the Agency concluded it would be appropriate to present the petition to its Orthopaedic and Rehabilitation Devices Advisory Panel during an upcoming meeting tentatively scheduled for September 8 and 9, 2005; regardless of whether RS Medical responded to the comments with an amendment to the petition.

While RS Medical agrees that the panel could conduct a substantive evaluation of the petition, we also recognize the value of responding to the comments prior to the panel’s deliberations. Thus, we request that the petition not be considered at the upcoming panel meeting, but at the following meeting. This will enable RS Medical to fully respond to comments, and improve panel deliberations.

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We recognize that this request will delay FDA's review of the petition. Thus, we believe it is appropriate for the Agency to put its review on hold for the purpose of calculating review time, until we amend the petition.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Carroll", written in a cursive style.

William Carroll  
Vice President, Research and Development