

## **Docket 2005P-0121 for the RS Medical Petition to Reclassify the Non-invasive Bone Growth Stimulator**

FDA issues rules that establish or modify the way it regulates foods, drugs, biologics, cosmetics, radiation-emitting electronic products, and medical devices--commodities close to the daily lives of all Americans. FDA's mission is to promote and protect the public health. Its rulemaking process, including review of petitions submitted to the agency is open to public comment. FDA seeks public comment on its proposed regulations and the petitions under agency review and carefully considers these comments.

The Division of Dockets Management (website <http://www.fda.gov/ohrms/dockets/>) is FDA's official repository for the administrative proceedings, rule-making, and petitions. A public docket is established for each administrative proceeding, rulemaking topic and petition. Information regarding making a comment on any docket topic can be found within "Making Your Voice Heard at FDA: How to Comment on Proposed Regulations and Submit Petitions" (<http://www.fda.gov/ohrms/dockets/default.htm>).

A list of the public comments received regarding RS Medical's petition to reclassify the non-invasive bone growth stimulator device from class III into class II is given below. The website for this petition docket is: <http://www.fda.gov/ohrms/dockets/dockets/05p0121/05p0121.htm>, (updated on April 25, 2006).

For your convenience, paper copies of these three website pages are provided. A CD copy of the petition docket comments is also provided.

<b>Document Number</b>	<b>Received Date</b>	<b>Filed Date</b>	<b>Submitter Code</b>	<b>Submitter</b>	<b>Description</b>
CCP1	3/29/05	2/09/05	Device Industry	RS Medical	Original Petition
ACK 1	3/30/05	3/30/05	Federal Government	HFA-305 to RS Medical	Acknowledgement of Petition Receipt
C1	7/01/05	6/28/05	Health Professional	H. Yuan, M.D.	Comments in Response to Reclassification
C2	7/11/05	7/08/05	Drug Industry	EBI A Biomet Company	Comments in Response to Reclassification
TS1	7/21/05	7/21/05	Private Industry	King & Spalding LLP	Presentation to FDA
C3	7/27/05	7/26/05	Academia	N. Partridge, PhD	Comments in Response to Reclassification
LET1	8/03/05	8/03/05	Federal Government	HFZ-1 to RS Medical	Interim Response: Continued Review
LET2	8/04/05	8/04/05	Device Industry	RS Medical	Request for "Hold" Status
LET3	8/18/05	8/18/05	Federal Government	HFZ-400 to RS Medical	FDA Concerns for Consideration
C4	8/17/05	8/17/05	Private Industry	BGS Reclassification Response Group	Comments in Response to Reclassification
C5	8/18/05	8/12/05	Private Industry	Texas Back Institute	Comments in Response to Reclassification

C6/SUP1	10/06/05	10/12/05	Device Industry	dj Ortho™	Comments in Response to Reclassification
AMD1	12/08/05	11/30/05	Device Industry	RS Medical	Amendment to Petition
C7	8/19/05	10/12/05	Health Professional	Raymond J Linovitz, MD., FACS	Comments in Response to Reclassification
C8	8/16/05	10/13/05	Health Professional	John O. Bishop, MD, PA.	Comments in Response to Reclassification
C9	2/14/05	2/10/06	Private Industry	BGS Reclassification Response Group	Comments in Response to Reclassification
C10	2/17/06	2/17/06	Private Industry	EBI., L.P.	Comments in Response to Reclassification
C11	3/09/06	3/07/06	Private Industry	BGS Reclassification Response Group	Comments in Response to Reclassification
TS2	4/10/06	4/10/06	Private Industry	BGS Reclassification Response Group	Presentation to FDA