



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1350 Piccard Drive
Rockville, Maryland 20850

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AUG 01 2005

William Carroll
RS Medical
14401 SE First Street
Vancouver, WA 98684

Re: Docket No. 2005P-0121

Dear Mr. Carroll:

This is an interim response to your petition filed by the Food and Drug Administration (FDA) on February 9, 2005. In your petition, you request that FDA reclassify the Non-invasive Bone Growth Stimulator from Class III (premarket approval) to Class II (special controls) in accordance with section 513 (e) of the Federal Food, Drug and Cosmetic Act; 21 CFR 860.123 and 21 CFR 860.130.

We are still considering the issues presented in your petition and are unable to provide a final response at this time. We expect to issue a final response in the near future.

If you have any questions about this interim response, please contact Rosa M. Gilmore of our Regulations Staff at (301) 827-2970.

Sincerely yours,

Linda S. Kahan
Deputy Director
Center for Devices and
Radiological Health

2005P-0121

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