



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

March 30, 2005

FILE COPY

Mr. William Carroll
RS Medical
14401 SE First Street
Vancouver, Washington 98684

Dear Mr. Carroll:

Your petition requesting that the Non-invasive Bone Growth Stimulator be reclassified from Class III to Class II in accordance with Section 513(e) of the Food, Drug and Cosmetic Act (FDCA), 21 CFR 860.123 and 21 CFR 860.130, was received by this office on 03/29/2005. It was assigned docket number 2005P-0121/CCP 1 and it was filed on 02/09/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0121

ACK1