



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

July 6, 2006

Dr. Fremont P. Wirth
American Association of Neurological Surgeons
5550 Meadows Drive
Rolling Meadows, Illinois 60008

Dear Dr. Wirth:

Your petition requesting the Food and Drug Administration to Exempt the Class II device Cranial Orthoses from Premarket Notification Requirements under section 510(m) (2), was received by this office on 07/06/2006. It was assigned docket number 2006P-0085/CP1 and it was filed on 07/06/2006. 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,

A handwritten signature in black ink that reads "Jennie C. Butler".

Jennie C. Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management

2006P.0085

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