AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS
THOMAS A. MARSHALL, *Executive Director*
5550 Meadowbrook Drive
Rolling Meadows, IL 60008
Phone: 888-566-AANS
Fax: 847-378-0600
info@aans.org

President
DONALD O. QUEST, MD
Columbia University
New York, New York

CONGRESS OF
NEUROLOGICAL SURGEONS
LAURIE BEHNCKE, *Executive Director*
10 North Martingale Road, Suite 190
Schaumburg, IL 60173
Phone: 877-517-1CNS
FAX: 847-240-0804
info@1CNS.org

President
RICHARD G. ELLENBOGEN, MD
University of Washington
Seattle, Washington

May 10, 2006

Food and Drug Administration
Division of Dockets Management
HFA-305
5630 Fishers Lane, Room 1601
Rockville, MD 20852

Dear Sir or Madame:

RE: Orthopedic Devices: Reclassification of the Intervertebral Body Fusion Device.
Docket No. 2006N--0019

On behalf of the American Association of Neurological Surgeons (AANS), we appreciate the opportunity to comment on the above referenced notice, which was published in the *Federal Register* on February 9, 2006.

We support the FDA proposal to reclassify intervertebral body fusion devices that contain bone grafting material from class III to class II. We believe that these devices are safe and effective when implanted by appropriately trained surgeons in carefully selected patients.

With regard to the proposal to retain intervertebral body fusion devices containing therapeutic biologic (e.g. bone morphogenic protein) in class III, we would suggest that the device itself is not substantially different than the device used for the bone grafting material and would recommend de-linking the device from the material placed in the device. In other words, we feel the "cage" itself should be reclassified to class II even if the FDA believes that the therapeutic biologic should remain in class III.

Thank you for your time and attention.

Sincerely,

Donald O. Quest, MD, President
American Association of Neurological Surgeons

Richard G. Ellenbogen, MD, President
Congress of Neurological Surgeons

Washington Office Contact
Catherine Jeakle Hill, Senior Manager for Regulatory Affairs
AANS/CNS Washington Office
725 15th Street, NW, Suite 800
Washington, DC 20005
Office: 202-628-2072
Email: chill@neurosurgery.org