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
WILLIAM T. COULDWELL, MD, PHD
Salt Lake City, Utah

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

President
ALI R. REZAI, MD
Columbus, Ohio

May 22, 2013

Sara J. Anderson, MPH, OCN
Regulatory Officer, LCDR, USPHS
Office of Device Evaluation
FDA Center for Devices and Radiological Health
Silver Spring, MD 20993

Dear Ms. Anderson:

RE: Orthopaedic and Rehabilitation Devices Panel Meeting to Consider Reclassification of Pedicle Screw Systems

The American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), and the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves appreciate the opportunity to provide comments to the Food and Drug Administration for the May 22, 2013, Orthopaedic and Rehabilitation Devices Panel consideration of re-classification of pedicle screw spinal systems for the treatment of degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5-S1, or degenerative spondylolisthesis with objective evidence of neurologic impairment. We support the re-classification of the pedicle screw spinal system to Class II for the indications mentioned above.

Class II is an appropriate classification as it is defined as a low to moderate risk device with known potential risks, which can be effectively mitigated with Special Controls such as guidance documents and labeling. Pedicle screw fixation of the spine has a long history of clinical use. In the early 1960's in Europe, Raymond Roy-Camille, MD, applied pedicle screws to the lumbar spine for the treatment of fractures. In the United States (U.S.), Paul Harrington, MD, was the first to initiate use of pedicle screws in 1969 to reduce and stabilize high grade lumbar spondylolisthesis. Pedicle screw systems for various spinal indications were first marketed in the U.S. before the 1976 Medical Device Amendments (MDA), as pre-amendment devices.

Surgeons in the U.S. have utilized pedicle screw spinal systems for the treatment of Grade III and IV spondylolisthesis since the 1980's. These systems have allowed the surgeons to safely stabilize the spine for the purposes of arthrodesis, much as they have done for lesser-grade spondylolisthesis. In many patents, there are no adequate alternatives to the use of these systems.

More than 10 years ago in the July 27, 1998 Federal Register (and as amended May 22, 2001), the FDA published a final rule classifying certain previously unclassified pre-amendment pedicle screw spinal systems for the thoracic, lumbar and sacral spine. Pedicle screws for the following indications are Class II: spondylolisthesis, trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudarthrosis; and failed previous fusion in skeletally mature patients.

WASHINGTON OFFICE
KATIE O. ORRICO, *Director*
725 Fifteenth Street, NW, Suite 500 Washington, DC 20005
Phone: 202-628-2072 Fax: 202-628-5264 E-mail: korrico@neurosurgery.org

For the indications of degenerative disc disease and spondylolisthesis, other than severe spondylolisthesis (grade 3 or 4), and for degenerative spondylolisthesis without objective evidence of neurological impairment, the devices are currently Class III. We believe that this indication should be changed to Class II, as general and special controls, defined through guidance documents, provide reasonable assurance of safety and effectiveness.

Again, thank you for this opportunity to comment and we look forward to seeing your final position pertaining to this proposed topic.

Sincerely,

William T. Couldwell, MD PHD, President
American Association of Neurological Surgeons

Ali R. Rezai, MD, President
Congress of Neurological Surgeons

Michael W. Groff, MD, Chair
AANS/CNS Joint Section on Disorders of the Spine
and Peripheral Nerves

Staff Contact:
Catherine Jeakle Hill
Senior Manager, Regulatory Affairs
AANS/CNS Washington Office
725 15th Street, NW, Suite 500
Washington, DC 20005
Phone: 202-446-2026
Fax: 202-628-5264
e-mail: chill@neurosurgery.org