

AMERICAN ASSOCIATION OF  
NEUROLOGICAL SURGEONS

KATHLEEN T. CRAIG, *Executive Director*  
5550 Meadowbrook Drive  
Rolling Meadows, IL 60008  
Phone: 888-566-AANS  
Fax: 847-378-0600  
info@aaans.org



CONGRESS OF  
NEUROLOGICAL SURGEONS

REGINA SHUPAK, *CEO*  
10 North Martingale Road, Suite 190  
Schaumburg, IL 60173  
Phone: 877-517-1CNS  
FAX: 847-240-0804  
info@1CNS.org

*President*  
FREDERICK A. BOOP, MD  
Memphis, Tennessee

*President*  
RUSSELL R. LONSER, MD  
Columbus, Ohio

June 8, 2016

Genevieve Hill  
FDA, Center for Devices and Radiological Health  
10903 New Hampshire Avenue  
Building 66, Room 1457  
Silver Spring, MD 20993-0002

**Subject: Proposed Rule; Classification of Posterior Cervical Screws, FDA-2015-N-3785**

Dear Ms. Hill:

On behalf of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), we appreciate the opportunity to comment on the above referenced proposed rule to classify posterior cervical screw systems as class II devices. Since 2001, the FDA has regulated posterior cervical screw systems as unclassified preamendments devices. The use of posterior cervical screw systems has been the standard of care for surgical management of cervical spine disorders arising from tumor, trauma, degenerative disease and deformity for approximately 20 years. Organized neurosurgery supports the appropriate classification of these devices. As such, we presented our views on the subject at the September 21, 2012, Orthopaedic Devices Panel meeting.

We commend FDA staff for issuing the proposed rule. The anatomical and biomechanical advantages, the current literature and the experience in clinical practice confirm that posterior cervical screws have become the standard of care when instrumenting the posterior cervical spine.

Thank you for your time and attention. We appreciate the dedication and expertise of the FDA staff and look forward to continuing to work together on behalf of our patients.

Sincerely,

Frederick A. Boop, MD, President  
American Association of Neurological Surgeons

Russell R. Lonser, President  
Congress of Neurological Surgeons

**Staff Contact:**

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

WASHINGTON OFFICE  
KATIE O. ORRICO, *Director*

725 Fifteenth Street, NW, Suite 500  
Phone: 202-628-2072 Fax: 202-628-5264

Washington, DC 20005  
E-mail: korricco@neurosurgery.org