

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS

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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
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