

Classification of Facet Screw Spinal Device Systems

FDA Questions

Orthopaedic and Rehabilitation Devices Panel of Medical Devices Advisory Committee
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1. FDA has identified the following risks to health for facet screw spinal device systems:

Loosening/migration due to device failure or failure at the bone/implant interface – Components may deform, fracture, wear, loosen, or disassemble, resulting in a mechanical or functional failure; this may result in back/leg pain, neurologic deficit/injury, or loss of correction. Components may loosen, migrate, or disengage from the bone; this may result in back/leg pain, neurological deficit/injury, or loss of correction.

Tissue injury – Intraoperative and post-operative risks of tissue injury include: Bone fracture, injury to blood vessels or viscera, neurologic injury, dural tear or cerebrospinal fluid leak and skin penetration or irritation, post-operative wound problems including infection, and hematoma/seroma.

Adverse tissue reactions – Device material(s) may elicit adverse tissue reactions, such as foreign body response, metal allergy, and metal toxicity.

Use error/Improper device use – Risks of device malposition may include difficulty or inability to implant the device components or incorrect placement of the device.

Pseudarthrosis due to device failure or failure at the bone/implant interface – The risk of nonunion, or pseudarthrosis, signifies failure of bony fusion and potential instability or pain.

Adverse clinical sequelae – Adverse clinical sequelae may include the risk of new or unresolved pain, new or worsened neurologic deficit/injury, or loss of correction.

Please comment on whether you agree with inclusion of all of the risks in the overall risk assessment of the facet screw spinal device systems under product code “MRW”. In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these facet screw spinal device systems.

2. Section 513 of the Food, Drug, and Cosmetic Act states a device should be Class III if:

- insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls would provide such assurance, AND

- if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

A device should be Class II if:

- general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness, AND
- there is sufficient information to establish special controls to provide such assurance.

A device should be Class I if:

- general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
- insufficient information exists to:
 - determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
 - establish special controls to provide such assurance, BUT
 - I. is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and
 - II. does not present a potential unreasonable risk of illness or injury.

FDA believes general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness and sufficient information exists to establish special controls to adequately mitigate the risks to health and provide reasonable assurance of device safety and effectiveness for this device type. As such, FDA believes that Class II is the appropriate classification for facet screw spinal device systems. Following is a risk/mitigation table which outlines the identified risks to health for this device type and the recommended controls to mitigate the identified risks.

Risk/mitigation recommendations for facet screw spinal device systems under product code “MRW”

Identified Risk	Recommended Mitigation Measure
Loosening/migration due to device failure or failure at the bone/implant interface	Design Characteristics Biocompatibility Non-clinical Performance Testing Labeling
Tissue injury	Labeling
Adverse tissue reactions	Design Characteristics Biocompatibility Sterilization/Reprocessing Validation

Identified Risk	Recommended Mitigation Measure
	Labeling
Use error/Improper device use	Labeling
Pseudoarthrosis due to device failure or failure at the bone/implant interface	Non-clinical Performance Testing Biocompatibility Labeling
Adverse clinical sequelae	Labeling

Please discuss whether the identified special controls for facet screw spinal device systems appropriately mitigate the identified risks to health and whether additional or different special controls are recommended:

1. Design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use.
 2. Non-clinical performance testing must demonstrate the mechanical function and durability of the implant.
 3. Device must be demonstrated to be biocompatible.
 4. Validation testing must demonstrate the cleanliness and sterility of, or the ability to clean and sterilize, the device components and device-specific instruments.
 5. Labeling must bear all information required for the safe and effective use of the device, specifically including the following:
 - i) A clear description of the technological features of the device, including identification of device materials and the principles of device operation;
 - ii) Intended use and indications for use including levels of fixation;
 - iii) Identification of magnetic resonance (MR) compatibility status;
 - iv) Cleaning and sterilization instructions for devices and instruments that are provided non-sterile to the end user; and
 - v) Detailed instructions on each surgical step, including device removal.
- 3. Please discuss whether you agree with FDA’s proposed classification of Class II with special controls for facet screw spinal devices. If you do not agree with FDA’s proposed classification, please provide your rationale for recommending a different classification.**