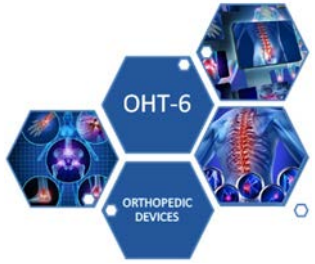

U.S. FOOD & DRUG ADMINISTRATION

Classification of Facet Screw

Spinal Device Systems Under Product Code "MRW"

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Division of Spinal Devices

Office of Health Technology 6- Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

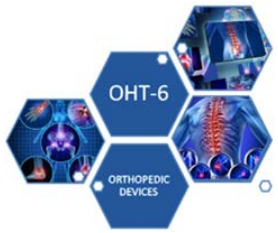
Food and Drug Administration

Orthopaedic and Rehabilitation Devices

Panel Meeting

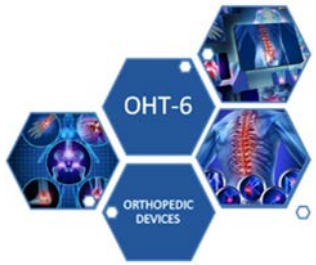
September 8, 2020

Center for Devices and Radiological Health
CDRH



Outline

- Device Description
- Indications for Use
- Regulatory History
- Clinical Background
- Literature Review
- Medical Device Reports
- Risks to Health & Mitigations
- Classification
- Proposed Special Controls
- FDA Questions



Device Description

- Facet screw spinal device systems are intended to stabilize the spine to promote fusion through immobilization of the facet joints in the cervical, thoracic, and lumbosacral spine

- They consist of partially or fully threaded bone fixation screws, used without longitudinal members (e.g., spinal rods, spinal plates). They are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136 or stainless steel per ASTM F138

- These devices are reportedly used unilaterally or bilaterally, with or without bone graft material and have been cleared with other accessories (e.g., washers and cross-connectors). When used unilaterally, these devices have been described as used contralaterally to posterior spinal instrumentation

Device Description (Cont'd)

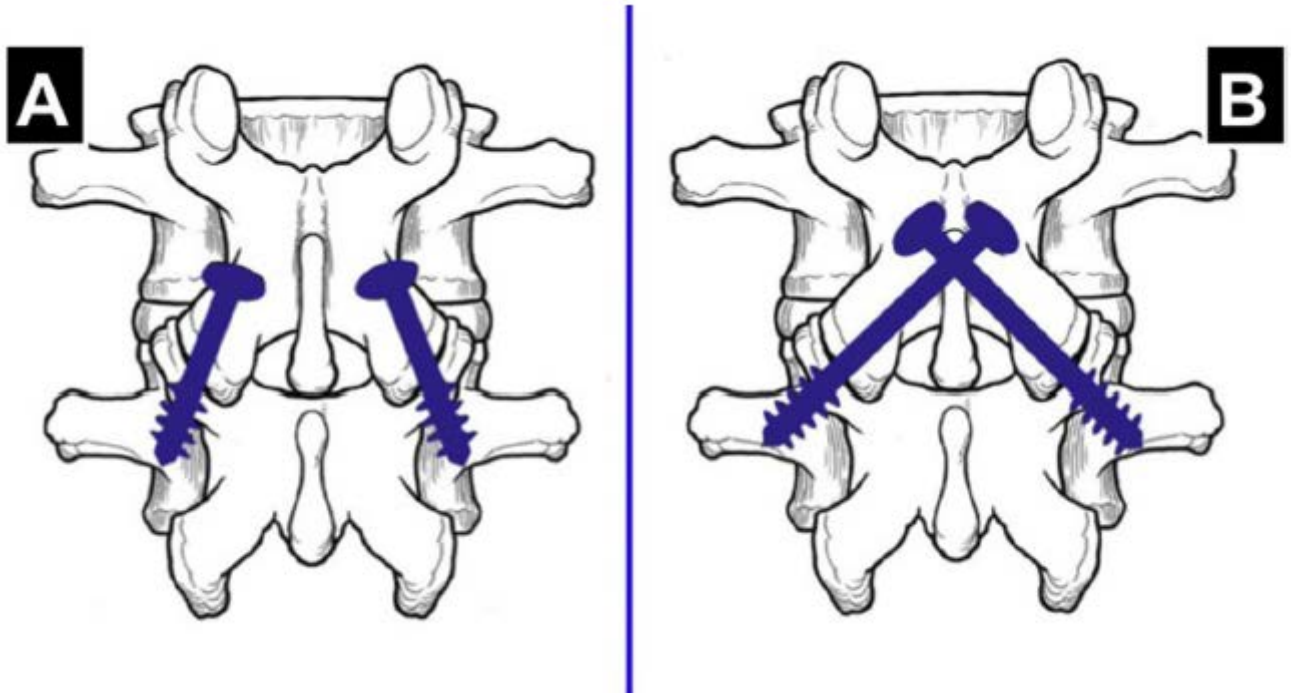
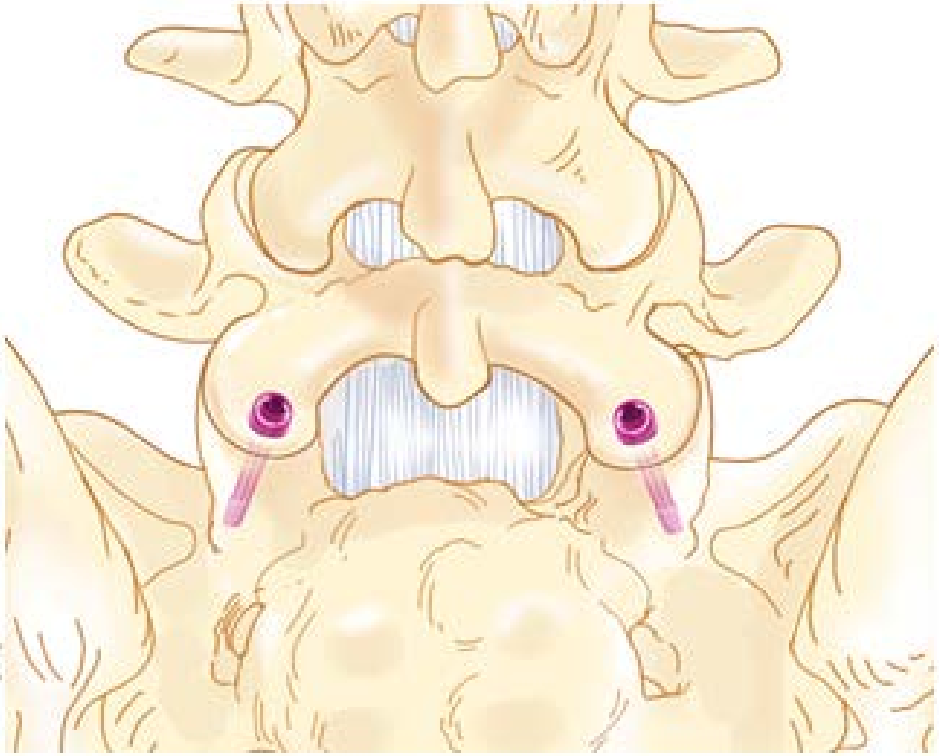
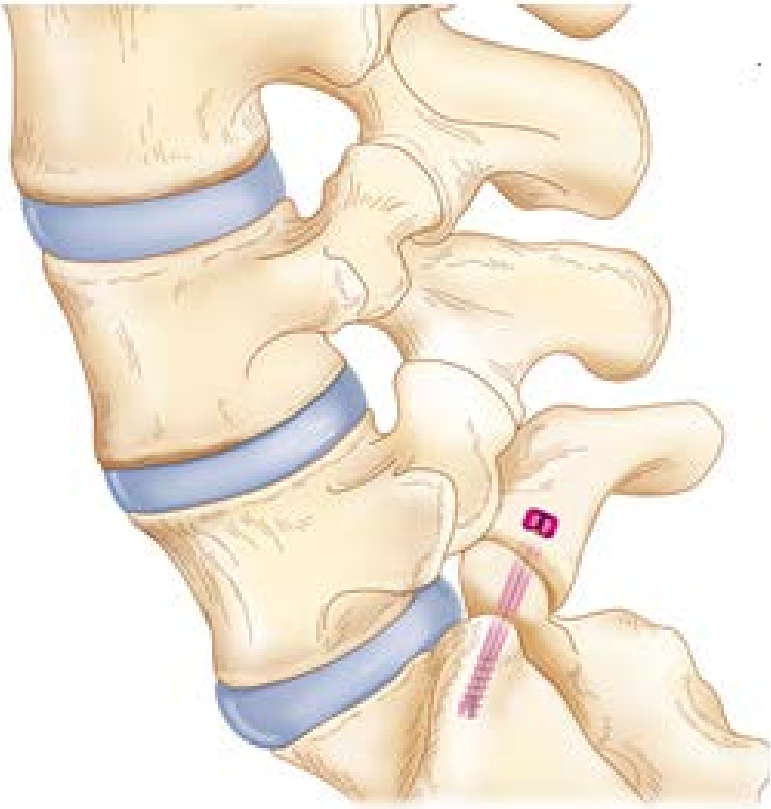


Fig. 5. Posterior facet screw fixation. In A the "true transfacet" technique, as proposed by Boucher in 1959, entailing use of two screws (for each level, one per side), traversing the facets vertically from medial to lateral. In B the "translaminar transfacet" technique as proposed by Magerl in 1984. Compared to Boucher's proposal, screws are significantly longer because the entry point is at the base of the contralateral spinous process.

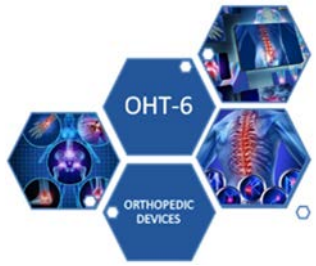
G. Bonaldi et al. (2015) Minimally-Invasive Posterior Lumbar Stabilization for Degenerative Low Back Pain and Sciatica. A Review. European Journal of Radiology, 84, 789-798.

Device Description (Cont'd)





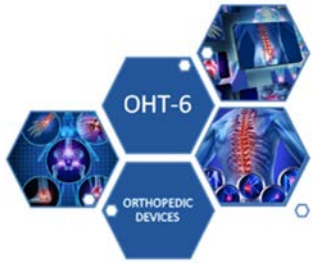
Transfacet Technique – Globus Medical



Indications for Use

These devices have been cleared as an adjunct to fusion for the following indications for use:

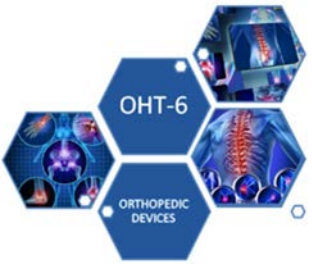
- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- Degeneration of the facets with instability
- Trauma including spinal fractures and/or dislocations
- Pseudoarthrosis or failed previous fusion which are symptomatic, or which may cause secondary instability or deformity
- Spondylolisthesis/spondylolysis



Regulatory History

- The first facet screw spinal system cleared under product code “MRW” was found substantially equivalent to a pre-amendments predicate device on February 28, 1997

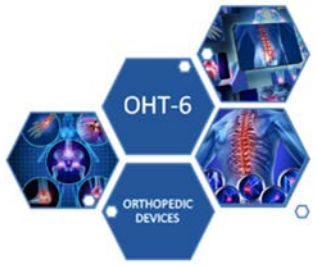
- To date, the FDA has cleared a total of 55 devices under the MRW product code



Clinical Background

- Facet screws are one type of implantable spinal device currently available for operative treatment of specific spinal conditions where stabilization of spinal segments as an adjunct to fusion or permanent immobilization is sought

- Facet screws provide a biomechanically equivalent method of spinal fixation which potentially avoids the need for implantation of longitudinal spinal rods

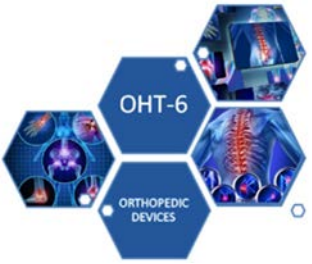


Literature Review

A systematic literature review was conducted in an effort to gather any published information regarding the safety and effectiveness of facet screw spinal device systems under product code “MRW.”

The literature review assessed the safety and effectiveness of bilateral, unilateral and hybrid implantation of facet screws in terms of:

- Fusion Rates
- Improvement in Pain
- Disability Scores (e.g., VAS, NDI, ODI)
- Safety – Adverse Events

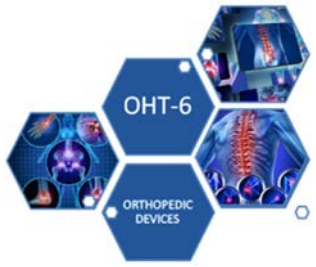


Literature Review – Effectiveness Assessment

- Publications reported fusion rates for the bilateral, unilateral and hybrid facet screw use, which ranged from 93.5%-100%

- Improvement in VAS and ODI scores were also reported in the referenced publications.

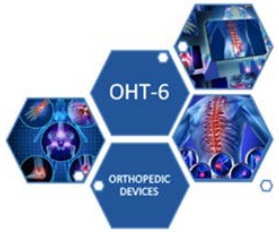
- Additionally, several publications reported no significant differences in fusion rates or pain and disability scores when compared to traditional Class II bilateral pedicle screw use/instrumentation.



Literature Review – Safety Assessment

Reported Adverse Events Include:

- Fracture/Breakage
- Screw loosening
- Screw Pull-Out
- Screw Misplacement
- Infection
- Non-Fusion
- Reoperation
- Foraminal Encroachment
- Facet Injury
- Lamina Invasion/Penetration

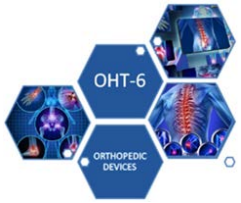


Literature Review- Summation

- The reported adverse events are similar to those reported with the use of other Class II spinal instrumentation systems and do not raise additional concerns regarding facet screw spinal device systems.

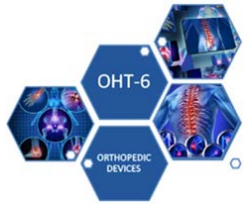
- The facet screw spinal device systems were reported to have similar safety-and effectiveness profiles as pedicle screw systems when used as adjuncts to fusion for the permanent immobilization of spinal segments.

- Based on the review of the published literature, the clinical evidence supports a reasonable assurance of safety and effectiveness for facet screw use as a method of providing immobilization and stabilization of the spine as an aid for fusion.



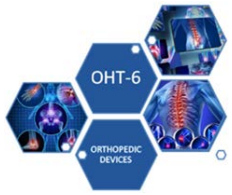
Medical Device Reports

- Medical Device Reporting (MDR): the mechanism for the FDA to receive significant medical device adverse events from:
  - mandatory reporters (manufacturers, importers and user facilities)
  - voluntary reporters (health care professionals, patients, consumers)



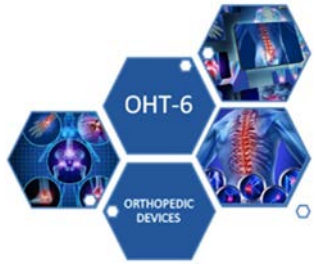
Medical Device Reports

- MDR reports can be used effectively to:
  - Establish a qualitative snapshot of adverse events for a specific device or device type
  - Detect actual or potential device problems used in a “real world” setting/environment, including:
    - rare, serious, or unexpected adverse events
    - adverse events that occur during long-term device use
    - adverse events associated with vulnerable populations
    - off-label use
    - user error



Medical Device Reports

- Limitations
  - Under reporting of events
  - Potential submission of incomplete, inaccurate, untimely, unverified, or biased data
  - Incidence or prevalence of an event cannot be determined from this reporting system alone
  - Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report
  - MAUDE data does not represent all known safety information for a reported medical device

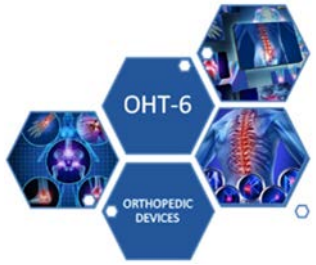


Risk Identification

MAUDE (Manufacturer And User Facility Device Experience) Database reviewed for product code "MRW" from February 28, 1997 (first clearance) through January 2020:

96 adverse events:

- 51% (49/96) Instrument (Implantation) Malfunctions
- 26% (25/96) Device (Implant) Specific (fracturing, loosening or migration)
- 23% (22/96) Not specified as instrument or device specific (No deaths or serious neurological events were reported)

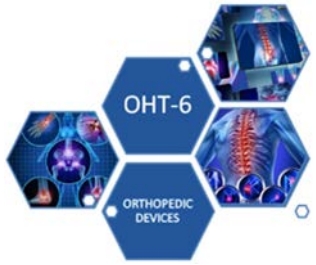


Risk Identification (Cont'd)

FDA Medical Device Recall Database (from November 2002 through January 2020):

- 3 recalls total for product code "MRW" – all instrument related

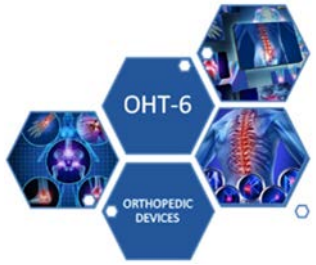
In summation, based on the totality review of the literature, as well as the MAUDE and Recall Databases, FDA identifies no new general safety concerns related to facet screw spinal device systems as a product class.



Risk Identification (Cont'd)

- **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



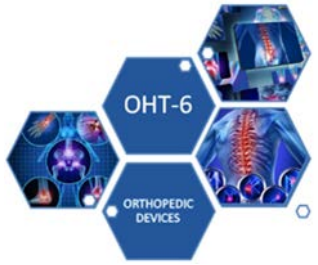
Risk Identification (Cont'd)

- **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.

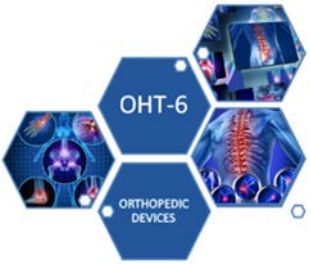
- **Pseudarthrosis due to device failure or failure at the bone/implant interface** – The risk of nonunion, or pseudarthrosis, signifies failure of bony fusion and potential instability or pain.

- **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



Risks and Mitigations

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 • Sterility • 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



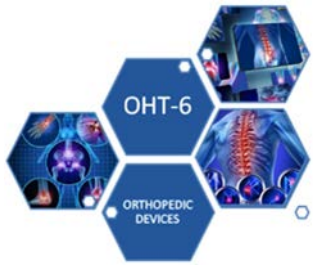
Proposed Classification Regulation

FDA

21 CFR 888.3078 Facet Screw Systems

(a) Identification. Facet screws are bone screws consisting of solid or cannulated designs with fully or partially threaded screw shafts used without longitudinal members (e.g. spinal rods, spinal plates) indicated for use for stabilization of the spine to promote fusion by immobilization of the facet joints. Facet screws may be used with additional components that are part of the device system such as facet washers and accessory instrumentation.

(b) Classification. Class II (special controls). The special controls for this device are as follows.



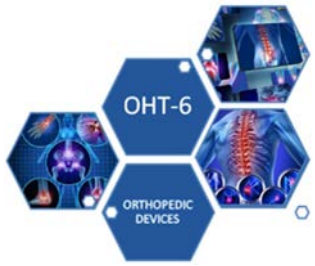
Proposed Special Controls

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.

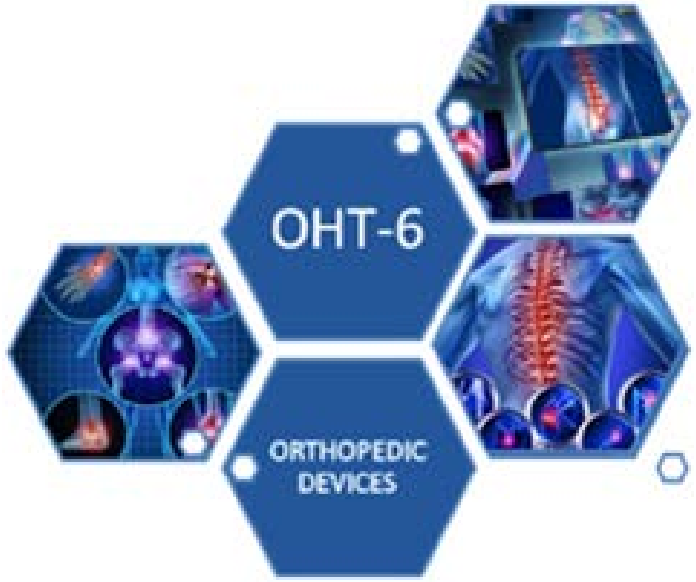


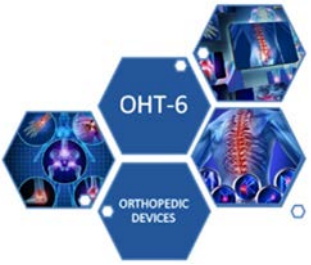
Proposed Special Controls (Cont'd)

5. Labeling must bear all information required for the safe and effective use of the device, specifically including the following:

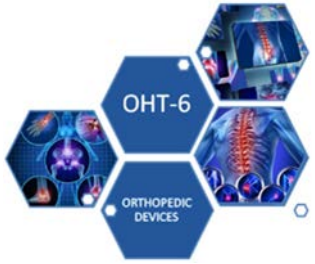
- Clear description of the technological features of the device, including identification of device materials and the principles of device operation;
- Intended use and indications for use including levels of fixation;
- Identification of magnetic resonance (MR) compatibility status;
- Cleaning and sterilization instructions for devices and instruments that are provided non-sterile to the end user; and
- Detailed instructions on each surgical step, including device removal.

Thank You



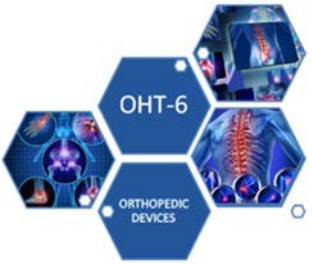


Questions to Panel



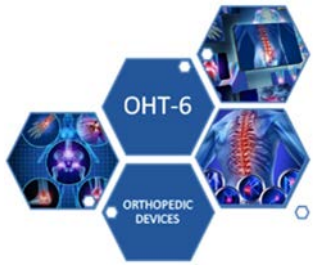
Question 1 to Panel

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.



Question 2 to Panel

Please discuss whether the identified special controls appropriately mitigate the identified risks to health and whether additional or different special controls are recommended.



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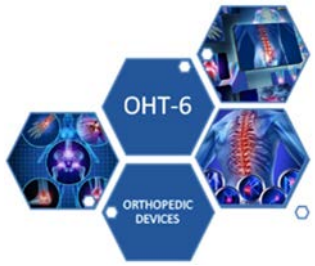

Proposed Special Controls (Cont'd)

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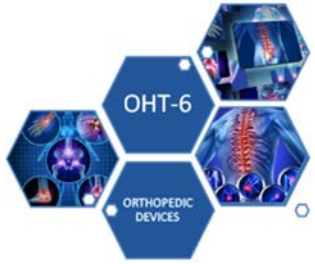
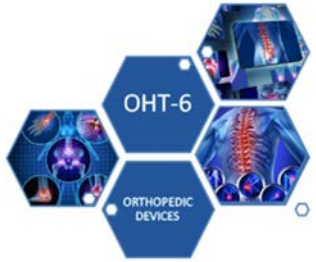


Question 3 to Panel

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.



End of Panel Questions for Product Code "MRW"