FDA Executive Summary

Prepared for the September 8-9, 2020 Meeting of the Orthopaedic and Rehabilitation Devices Panel

Classification of Facet Screw Spinal Device Systems

Product Code: MRW (System, Facet Screw Spinal Device)

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1. Introduction

Per Section 513(b) of the Food, Drug, and Cosmetic Act (the Act), the Food and Drug Administration (FDA) is convening the Orthopaedic and Rehabilitation Devices Panel (the Panel) for the purpose of obtaining recommendations regarding the classification of facet screw spinal device systems, a pre-amendments device type that remains unclassified. Specifically, the FDA will ask the Panel to provide recommendations regarding the regulatory classification of facet screw spinal device systems under product code "MRW." The device names and associated product codes are developed by the Center for Devices and Radiological Health (CDRH) in order to identify the generic category of a device for FDA. While most of these product codes are associated with a device classification regulation, some product codes, including "MRW" remain unclassified.

FDA is holding this panel meeting to obtain input on the risks to health and benefits of facet screw spinal device systems under product code "MRW." The Panel will discuss whether the facet screw spinal device systems under product code "MRW" should be classified into Class III (subject to General Controls and Premarket Approval), Class II (subject to General and Special Controls) or Class I (subject only to General Controls). If the Panel believes that classification into Class II is appropriate for the facet screw spinal device systems under product code "MRW," the Panel will also be asked to discuss appropriate controls that would be necessary to mitigate the risks to health.

1.1 Current Regulatory Pathways

Facet screw spinal device systems are a pre-amendment, unclassified device type. This means that this device type was marketed prior to the Medical Device Amendments of 1976 but was not classified by the original classification panels. Currently these devices are being regulated through the 510(k) pathway and are cleared for marketing if their intended use and technological characteristics are "substantially equivalent" to a legally marketed predicate device. Since these devices are unclassified, there is no regulation associated with the product code.

1.2 Device Description

Facet screw spinal device systems consist of partially or fully threaded bone fixation screws, used without longitudinal members (e.g., spinal rods, spinal plates). These systems may include other features such as facet screw washers and cross-connectors.[1] These devices and associated surgical techniques have been described since the 1950s (Boucher, 1959; Montesano, Magerl et al., 1988). These devices are manufactured from, titanium alloy (Ti-6Al-4V ELI) per ASTM F136, or stainless steel per ASTM F138, and are intended to stabilize the spine to promote fusion through immobilization of the zygapophyseal, or facet, joints. These devices may be used unilaterally or bilaterally. When facet screw spinal device systems are used unilaterally, these devices are used in combination with posterior spinal screw instrumentation systems on the contralateral side of the spine. Posterior spinal screw instrumentation is regulated under different

[1] The facet screw cross-connector was cleared under K150223.

classifications from facet screw spinal device systems. Facet screw spinal device systems may be used in the cervical, thoracic, or lumbosacral spine, with or without bone graft material.

2. Regulatory History

Facet screw spinal device systems were manufactured by Zimmer Manufacturing Company prior to May of 1976 under the Townley Bone Graft Screw and Townley Compression Screw trade names. The first product code "MRW" device cleared under the 510(k) program, the Sofamor Danek Transfacetpedicular Screw Fixation System, was found substantially equivalent to the Zimmer pre-amendments predicate device on February 28, 1997 (K953076). To date, the FDA has cleared a total of 55 devices under the MRW product code.

Please refer to Table 1 for a listing of the manufacturers, device names, and associated 510(k) submission numbers for cleared facet screw spinal device systems under product code "MRW":

Table 1: 510(k) Clearances for Facet Screw Spinal Device Systems under Product Code "MRW"

510(k) Number	TRADE NAME	SPONSOR
K953076	TRANSFACETPEDICULAR SCREW FIXATION SYSTEM	SOFAMOR DANEK USAINC.
K994308	TOWNLEY TRANSFACET/INTRAPEDICULAR SCREW	NUVASIVE INC.
K001323	NUVASIVE PERCUTANEOUS TRANSFACET/INTRAPEDICULAR SCREW	NUVASIVE INC.
K003928	TOWNLEY TRANSFACETPEDICULAR SCREW FIXATION SYSTEM	MEDTRONIC SOFAMOR DANEK INC.
K012773	DISCOVERY FACET SCREW FIXATION SYSTEM	DEPUY ACROMED
K013829	TOWNLEY TRANSFACETPEDICULAR SCREW FIXATION SYSTEM	MEDTRONIC SOFAMOR DANEK INC.
K020411	NUVASIVE TRIAD FACET SCREW SYSTEM	NUVASIVE INC.
K021705	TOWNLEY TRANSFACEPEDICULAR SCREW FIXATION SYSTEM	MEDTRONIC SOFAMOR DANEK INC.
K031657	STRYKER SPINE OASYS BONE SCREW	HOWMEDICA OSTEONICS CORP.

510(k) Number	TRADE NAME	SPONSOR
K043351	4.5MM BONE-LOK FACET SCREW	TRIAGE MEDICAL INC
K051856	TRANS1 FACET SCREWS	TRANS1 INCORPORATED
K051949	4.5 MM LS FACET COMPRESSION DEVICE WITH POLYMER WASHER	TRIAGE MEDICAL INC.
K052043	3.8MM CS FACET COMPRESSION DEVICE	TRIAGE MEDICAL INC.
K061041	US SPINE FACET FIXATION SYSTEM	US SPINE
K062391	DISPOSABLE POSTERIOR LUMBAR STABILIZATION PROCEDURE KIT AND REUSABLE COMPRESSION TOOL	TRIAGE MEDICAL INC.
K071420	CHAMELEON FIXATION SYSTEM	SPINEFRONTIER INC.
K073515	TRANS1 FACET SCREWS	TRANS1 INCORPORATED
K082795	SINGLE USE PERPOS PLS SYSTEM BONE-LOK PLS IMPLANT	INTERVENTIONAL SPINE INC.
K083442	CORRIDOR FIXATION SYSTEM	GLOBUS MEDICAL INC.
K090767	PERPOS FCD-2 SYSTEM (SINGLE PATIENT USE) ANCHOR STABILIZER	INTERVENTIONAL SPINE INC.
K090865	LIFE SPINE FACET SCREW SPINAL SYSTEM	LIFE SPINE
K090952	ZYFUSE FACET FIXATION SYSTEM	GLOBUS MEDICAL INC.
K092464	SPINEOLOGY FACET SCREW SYSTEM	SPINEOLOGY INC.
K092568	SPARTAN S3 FACET SYSTEM	AMENDIA INC.
K100154	FIXCET SPINAL FACET SCREW SYSTEM	X-SPINE SYSTEMS INC.
K101284	NUVASIVE FACET SCREW SYSTEM	NUVASIVE INC.
K101364	LANX FACET SCREW SYSTEM	LANX INC.
K101762	VIPER F2 FACET FIXATION SYSTEM	DEPUY SPINE INC.
K101765	KYPHON ANCHOR FACET SCREW SYSTEM	MEDTRONIC SPINE LLC.
K102438	PRIMALOK FACET FIXATION SYSTEM	OSTEOMED L.P.
K110170	RAPTOR FACET FIXATION SYSTEM	ALPHATEC SPINE INC.
K112097	EXACTECH GIBRALT SPINE SYSTEM FACET SCREW	EXACTECH INC.
K113011	SPARTAN S3 FACET SYSTEM	AMENDIA INC.
K120340	VENUS FACET SCREW SYSTEM	APOLLO SPINE INC.
K120597	KOMPRESA FACET SCREW SYSTEM	CUSTOM SPINE INC.

510(k) Number	TRADE NAME	SPONSOR
K121551	RESOLUTE FACET SCREW SYSTEM	NEUROSTRUCTURES LLC
K121850	CHOICE SPINE FIXATION SYSTEM	CHOICE SPINE LP
K123218	ILLICO FS FACET FIXATION SYSTEM	ALPHATEC SPINE INC.
K123497	FACET SCREW SYSTEM	FACET-LINK INC.
K123932	ZYGAFIX SPINAL FACET SCREW SYSTEM	X-SPINE SYSTEMS INC
K130863	FACET SCREW SYSTEM	SPINAL USA
K131417	FACET FIXX	NEXXT SPINE LLC
K132126	SPECTRUM SPINE FENESTRATED FACET SCREW SYSTEM	SPECTRUM SPINE LLC
K132859	INTEGRA FACET FIXATION SYSTEM	SEASPINE INC.
K141376	INERTIA PEDICLE SCREW SYSTEM HONOUR SPACER SYSTEM FACET FIXX STRUXXURE ANTERIOR CERVICAL PLATE AND SCREWS	NEXXT SPINE LLC
K142980	PROFICIENT (TM) FACET SCREW SPINE SYSTEM	SPINE WAVE INC.
K150223	FACET-LINK STABILIZATION PLATFORM	FACET-LINK INC.
K152137	FACETBRIDGE SYSTEM	LDR SPINE USA
K161798	FACETBRIDGE® SYSTEM	LDR SPINE USA INC.
K163374	ALLY FACET SCREWS	PROVIDENCE MEDICAL TECHNOLOGY INC.
K173198	FACET SCREW FIXATION SYSTEM	U&I CORPORATION
K180729	FASET FIXATION SYSTEM	HUVEXEL CO. LTD
K183589	PMT FACET SCREW	PROVIDENCE MEDICAL TECHNOLOGY INC.
K192281	AEGIS ANTERIOR LUMBAR PLATE SYSTEM ALC DYNAMIZED FIXATION SYSTEM ANTERIOR ISOLA SPINE SYSTEM BOWTI ANTERIOR BUTTRESS STAPLE SPINAL SYSTEM DISCOVERY SCREW SYSTEM EXPEDIUM ANTERIOR SPINE SYSTEM FRONTIER ANTERIOR SCOLIOSIS SYSTEM KANEDA ANTERIOR SCOLIOSIS SYSTEM KANEDA SR ANTERIOR SPINAL SYSTEM	MEDOS INTERNATIONAL SARL

510(k) Number	TRADE NAME	SPONSOR
K192744	CORRIDOR FIXATION SYSTEM	GLOBUS MEDICAL INC.

3. Indications for Use

The Indications for Use (IFU) statement identifies the condition and patient population for which a device should be appropriately used.

The devices have been cleared for use in the treatment of any or all of the following indications for use as an adjunct to fusion:

- 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 fusions which are symptomatic, or which may cause secondary instability or deformity
- Spondylolisthesis/spondylolysis

4. Clinical Background

4.1 Disease Characteristics

The structural integrity of the spinal column may be compromised by a range of conditions such as spinal degeneration, trauma, prior surgical treatment, and spondylolysis/spondylolisthesis resulting in pain, neurologic dysfunction and decreased quality of life. Cervical, thoracic, and lumbar pain with or without neurologic symptoms resulting from degeneration or traumatic injury to the soft tissue and osseous structures of the spine are among the most common conditions requiring medical care. Traumatic spinal fractures are common, often resulting from high-energy falls, traffic accidents, and low energy falls.

4.2 Patient Outcomes

Patient outcomes following spinal fusion surgery are based on a combination of parameters including pain (e.g., neck or back, extremity) as measured by visual analog scale (VAS), functional improvement (e.g., Neck Disability Index (NDI), Oswestry Disability Index (ODI)), radiographic evidence of fusion (i.e., bridging bone) and complication rate, including subsequent surgical interventions and neurologic complications.

4.3 Currently Available Treatment

There are several alternatives for treatment of symptomatic spinal conditions defined by the indications for use described above. Treatment decision-making is

based on the etiology and severity of the specific spinal condition. Currently available treatment options include:

- Nonoperative alternative treatments, which include, but are not limited to, physical therapy, medications, braces, chiropractic care, bed rest, spinal injections, or exercise programs;
- Surgical alternative treatments that do not require implantable devices;
- Surgical alternative treatments utilizing another FDA-cleared or FDA-approved implantable device (e.g., thoracolumbosacral pedicle screw systems).

Spinal fusion or permanent immobilization of spinal motion segments due to surgical bony union is recommended as treatment for a broad range of degenerative, traumatic, and acquired conditions affecting the cervical, thoracic and lumbosacral spine. Use of spinal instrumentation systems to immobilize spinal segments and enhance bony union is associated with higher fusion rates compared to spinal fusion performed without the addition of spinal implants. Spinal instrumentation systems intended for fusion may be implanted in the anterior and/or posterior spine. Posterior spinal instrumentation systems may achieve spinal fixation through anchorage at various anatomical sites including the pedicles, laminae, facet joints and spinous processes. The most commonly used method for posterior spinal instrumentation intended to promote fusion is the use of posterior pedicle screw-rod systems. Facet screws spinal device systems provide a biomechanically equivalent method of spinal fixation that avoids the need for implantation of longitudinal spinal rods and is potentially less invasive compared to posterior spinal instrumentation using pedicle screw-rod systems.

4.4 Risks

FDA has identified the following risks to health associated with 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.

The Panel will be asked whether this list is a complete and accurate list of the risks to health presented by facet screw spinal device systems under product code MRW and whether any other risks should be included in the overall risk assessment of the device type

5. Literature Review

5.1 Methods

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."

On December 20, 2019, literature searches were performed to identify all published articles up to this date in three databases (Pubmed, Embase, and Web of Science Core Collection) and sought to address the following question:

> What is the safety and effectiveness of facet screw spinal instrumentation when used in the cervical, thoracic, and lumbar spinal regions?

The searches were limited to publications in English.

The Pubmed search used the following terms and yielded 145 literature references:

- (safety OR effectiveness OR adverse OR "adverse effects") AND (facet screw* OR facet fixation OR translaminar screw* OR translaminar facet screw* OR Boucher screw* OR Magerl translaminar facet screw* OR King facet screw* OR intrafacet screw* OR intrafacet fixation OR intrafacet fusion device* OR transfacet screw*) AND (thoracic spinal region OR thoracic OR thoracic spine OR lumbar spinal region OR lumbosacral region OR lumbosacral spine OR lumbar OR lumbar spine OR lumbar vertebrae OR lumbar vertebra OR thoracolumbar OR sacral OR thoracolumbosacral OR cervical spinal region OR cervical OR cervical spine) AND English [lang]

The EMBASE search used the following terms and yielded 64 literature references:

- ('safety'/exp OR 'safety' OR effectiveness OR adverse OR 'adverse effects') AND ('facet screw' OR 'facet screws' OR 'facet fixation' OR 'translaminar screw' OR 'translaminar screws' OR 'translaminar facet screw' OR 'translaminar facet screws' OR 'boucher screw' OR 'boucher screws' OR 'magerl translaminar facet screw' OR 'magerl translaminar facet screws' OR 'king facet screw' OR 'king facet screws' OR 'intrafacet screw' OR 'intrafacet screws' OR 'intrafacet fixation' OR 'intrafacet fusion device' OR 'intrafacet fusion devices' OR 'transfacet screw' OR 'transfacet screws') AND ('thoracic spinal region' OR thoracic OR 'thoracic spine'/exp OR 'thoracic spine' OR 'lumbar spinal region' OR 'lumbosacral region'/exp OR 'lumbosacral region' OR 'lumbosacral spine'/exp OR 'lumbosacral spine' OR lumbar OR 'lumbar spine'/exp OR 'lumbar spine' OR 'lumbar vertebrae'/exp OR 'lumbar vertebrae' OR 'lumbar vertebra'/exp OR 'lumbar vertebra' OR thoracolumbar OR sacral OR thoracolumbosacral OR ‘cervical spinal region’ OR cervical OR ‘cervical spine’/exp OR ‘cervical spine’) AND [English]/lim

The Web of Science Core Collection search used the following terms and yielded 112 literature references:

- TS=(safety OR effectiveness OR adverse OR “adverse effects”) AND TS=(facet screw* OR facet fixation OR translaminar screw* OR translaminar facet screw* OR Boucher screw* OR Magerl translaminar facet screw* OR King facet screw* OR intrafacet screw* OR intrafacet fixation OR intrafacet fusion device OR transfacet screw) AND TS=(thoracic spinal region OR thoracic OR thoracic spine OR lumbar spinal region OR lumbosacral region OR lumbosacral spine OR lumbar OR lumbar spine OR lumbar vertebrae OR lumbar vertebra OR thoracolumbar OR sacral OR thoracolumbosacral OR cervical spinal region OR cervical OR cervical spine)
  Limited to English

After duplicate articles were removed, the literature search of the above electronic databases yielded 236 literature references. Following a review of the titles and abstracts, a total of 28 literature references were determined to be relevant to the safety and effectiveness of facet screw instrumentation. Citations were excluded from the literature search based on the following criteria:

- Non-clinical study
- Unrelated to device or surgical technique
- Unrelated indications
- Non-fusion study

Of these 28 literature references, only 23 literature references were further reviewed in greater detail as 5 citations were unable to be located.

Upon further review of these articles, an additional six articles were determined not to be relevant to the safety and effectiveness of facet screw instrumentation and were excluded from this analysis, thus leaving a total of seventeen (17) publications for review.

5.2 Results

The literature review identified different types of facet screw use in the spine, which included bilateral, unilateral, and hybrid instrumentation (facet screws used contralateral to pedicle screw spinal systems that include use of a longitudinal member). Most publications (n=14) identified facet screw use with an intervertebral body fusion device (IBFD), autogenous bone graft, or allograft. Eleven (11) articles referenced bilateral facet screw use, one (1) article referenced unilateral facet screw use, and five (5) articles referenced the hybrid instrumentation.

The literature review assessed the effectiveness of bilateral and unilateral facet screw use in terms of fusion rates and improvement in pain and disability scores (e.g., VAS, NDI, ODI), and safety in terms of adverse events. For the publications that referenced use of hybrid instrumentation, treatment outcomes could not be directly attributed to the use of facet screw instrumentation alone. However, the use of hybrid instrumentation achieved comparable fusion rates compared to the use of traditional bilateral pedicle screw systems, which are Class II devices (e.g., Chin, 2017; Liu, 2016).

Seven (7) out of twelve (12) publications reported fusion rates for the bilateral and unilateral facet screw use, which ranged from 93.5%-100% (Table 2). 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 bilateral pedicle screw use (e.g., Rhee, 2015; Zeng, 2014). The bilateral and unilateral use of facet screw spinal device systems were reported to have similar safety profiles with respect to fusion rates and improvement in VAS and ODI scores when compared to traditional bilateral pedicle screws. While some publications did not specifically report fusion rates associated with the use of these devices, the authors of these publications still concluded that these devices provided clinical benefit to the patient or studied patient population. Furthermore, publications that specifically reported adverse events observed low rates that are comparable to those associated with other Class II spinal instrumentation systems (e.g., Aepli, 2009; Plotz, 1998).

Table 2: Facet Screw Fusion Rate Summary of Reviewed Publications

Author/Year	Facet Screw Instrumentation (Bilateral, Unilateral, Hybrid)	Fusion Rate
Cervical		
Coric D/1996	Bilateral	Not available
Rusconi A/2017	Bilateral	Not available
Takayasu M/2003	Bilateral	100%
Wu AM/2017	Bilateral	100%
Lumbar		
Aepli M/2009	Bilateral	Not available
Amoretti N/2013	Bilateral	100%
Cao Y/2015	Hybrid	95%
Chin KR/2017	Hybrid	100%
Goel A/2014	Bilateral	100%
Huang P/2017	Hybrid	87.9 %
Liu F/2016	Hybrid	89.3%
Luca A/2011	Bilateral	Not available
Luo P/2016	Hybrid	88.5%
Plotz GM/1998	Bilateral	Not available
Rhee JW/2015	Bilateral	100%
Shim CS/2005	Bilateral	100%
Zeng ZY/2014	Unilateral	93.5%

5.3 Adverse Events Associated with Facet Screw Spinal Device Systems

Adverse events reported for bilateral and unilateral facet screw use include screw fracture/breakage, screw loosening, screw pull-out, screw misplacement, infection, reoperation, non-fusion, foraminal encroachment, facet injury, and lamina invasion/penetration. However, these reported adverse events are similar to those observed with the use of other Class II spinal instrumentation systems and do not raise any additional concerns.

5.4 Overall Literature Review Conclusions

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.

6. Risks to Health Identified through Medical Device Reports (MDRs)

6.1 Overview of the MDR System

The MDR system provides FDA with information on medical device performance from patients, health care professionals, consumers and mandatory reporters (manufacturers, importers and device user facilities). The FDA receives MDRs of suspected device-associated deaths, serious injuries, and certain malfunctions. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. MDRs 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

Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the submission of incomplete, inaccurate, untimely, unverified, duplicated or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about the frequency of device use. Finally, the existence of an adverse event report does not definitely establish a causal link between the device and the reported event. Because of these limitations, MDRs comprise only one of the FDA's tools for assessing device performance. As such, MDR numbers and data should be taken in the context of the other available scientific information.

The Manufacturer and User Facility Device Experience (MAUDE) Database houses publicly releasable versions of the MDRs that is accessible on the FDA's website.

6.2 MDR Data: Facet Screw Spinal Device Systems

Individual MDRs for facet screw spinal device systems are reported through FDA's Manufacturer and User Facility Device Experience (MAUDE) Database, which houses mandatory reports from medical device manufacturers, importers and user facilities, as well as voluntary reports from entities such as health care professionals, patients and consumers.

A search of FDA's internal MDR Database using the product code "MRW" returned 96 reports from the start of the database through January 27, 2020. The majority of the adverse events reported were related to device instrument malfunctions (49/96; 51%). Fracture, loosening, and migration accounted for the device-specific adverse events (25/96; 26%); these are anticipated adverse events for spinal implants. The remaining reports (22/96; 23%) did not specifically describe events related to device failure. No deaths or serious neurological injuries were reported.

7. Recall History

7.1 Overview of Recall Database

The Medical Device Recall database contains Medical Device Recalls classified since November 2002. Since January 2017, it may also include correction or removal actions initiated by a firm prior to review by the FDA. The status is updated if the FDA identifies a violation and classifies the action as a recall and again when the recall is terminated. FDA recall classification may occur after the firm recalling the medical device product conducts and communicates with its customers about the recall. Therefore, the recall information posting date ("create date") identified on the database indicates the date FDA classified the recall, it does not necessarily mean that the recall is new.

7.2 Recall Results: Facet Screw Spinal Device Systems

A total of 3 recalls have been reported to date for devices with the product code "MRW", and are described below:

- Z-0008-2012: This recall was initiated due to reports of two of the Implant Driver Assembly tips breaking during surgery.

- Z-3034-2011: This recall was initiated due to Pull Pins that may disengage from the Facet Screw during the compression step, requiring that compression be completed with a device driver rather than the compression tool.

- Z-3033-2011: This recall was initiated due to Pull Pins that may disengage from the Facet Screw during the compression step, requiring that compression be completed with a device driver rather than the compression tool.

The recalls identified above are related to instrument issues and do not suggest that there are general safety concerns related to facet screw spinal device systems as a product class.

8. Summary

Considering the information available, the Panel will be asked to comment on whether facet screw spinal device systems under product code "MRW:"

meet the statutory definition of a Class III device:

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

- 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

or would be more appropriately regulated as Class II, in which:

- general and special controls, which may include performance standards, postmarket surveillance, patient registries and/or development of guidelines, are sufficient to provide a reasonable assurance of safety and effectiveness.

or as Class I, in which:

- the device is subject only to general controls, which include registration and listing, good manufacturing practices (GMPs), prohibition against adulteration and misbranding, and labeling devices according to FDA regulations.

For the purposes of classification, FDA considers the following items, among other relevant factors, as outlined in 21 CFR 860.7(b):

1. The persons for whose use the device is represented or intended;

2. The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;

3. The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and

4. The reliability of the device.

8.1 Special Controls

FDA believes that special controls, in addition to general controls, can be established to mitigate the risks to health identified, and provide a reasonable assurance of the safety and effectiveness of 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:

Table 3: Summary of Risks to Health and Proposed Special Controls for Facet Screw Spinal Device Systems

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 Labeling
Use error/Improper device use	Labeling

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

The Panel will be asked whether this list is a complete and accurate list of the risks to health presented for facet screw spinal device systems and whether any other risks should be included in the overall risk assessment of the device type.

Based on the identified risks and recommended mitigation measures, FDA believes that the following special controls would provide reasonable assurance of safety and effectiveness for facet screw spinal device systems under product code "MRW":

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.

If the Panel believes that Class II is appropriate for facet screw spinal device systems under product code "MRW," the Panel will be asked whether the identified special controls appropriately mitigate the identified risks to health and whether additional or different special controls are recommended.

8.2 Overview of Proposed Classification/FDA Recommendation

Based on the safety and effectiveness information gathered by the FDA, the identified risks to health and recommended mitigation measures, we recommend that facet screw spinal device

systems indicated for use for stabilization of the spine to promote fusion by immobilization of the facet joints be regulated as Class II devices.

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:

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.

Based on the available scientific evidence, the FDA will ask the Panel for their recommendation on the appropriate classification of facet screw spinal device systems under product code "MRW."

9. References

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