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510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
OSTEONICS® SPINAL SYSTEM -
TOP LOADING TRANSVERSE CONNECTOR ASSEMBLY

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:

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Device Identification

Proprietary Name:

Osteonics® Spinal System -
Top Loading Transverse Connector Assembly

Common Name:

Spinal Fixation Appliances

Classification Name and Reference:

Spinal Interlaminal Fixation Orthosis
21 CFR 888.3050

Predicate Device Identification

The Osteonics® Spinal System Top Loading Transverse Connector Assembly components are substantially equivalent to other legally marketed spinal system crosslinking (transversing) assembly components. These predicate components are part of the commercially available spinal systems stated below:

- Osteonics® Spinal System: Osteonics Corp.
- TSRH™ Spinal System: Sofamor Danek
- GDLH™ Posterior Spinal System: Sofamor Danek
- ISOLA Spinal System: Acromed

Device Description

The Osteonics® Spinal System Top Loading Transverse Connector Assembly allows a spinal construct on one side of the spine to be joined to another construct on the other side of the spine. This joining provides additional resistance to physiological forces such as unequal lateral loads, rotation, and isolated torsional movements. Construction of this assembly requires two Osteonics® Spinal System Top Loading Transverse Connectors, each with a Top Loading Connector Set Screw, and a Transverse Connector Bar. Each top loading transverse connector

joins one end of the transverse connector bar to one of the spinal rods of the longitudinal construct. The top loading connector set screw is used to secure the transverse assembly.

Intended Use

The subject components of the Osteonics® Spinal System Top Loading Transverse Connector Assembly are single-use devices which are sold non-sterile, and are intended for use only with other components of the commercially available Osteonics® Spinal System. The components of the Osteonics® Spinal System, including the additional components described herein, are available in either ASTM F-138 Stainless Steel (Type 316 LVM) or ASTM F-136 Ti6Al4V Alloy. Stainless steel components are intended for use only with other stainless steel components; Ti6Al4V alloy components are intended for use only with other Ti6Al4V alloy components.

The specific indications of the Osteonics® Spinal System, including the subject additional components, are stated below:

For non-pedicular use:

- Long and short curve scoliosis,
- Vertebral fracture or dislocation,
- Spondylolisthesis,
- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).

For pedicular use:

- When used as a pedicle screw system, the system is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. Pedicle screws are not intended for placement in pedicles above L3.

Statement of Technological Comparison

The components of the Osteonics® Spinal System Top Loading Transverse Connector Assembly share the same materials, intended uses and basic design concepts as that of the predicate devices. Fatigue and static testing demonstrates the mechanical and endurance properties of these components.