



Eminent Spine
Stephen Courtney
Chief Executive Officer
2004 Ventura Dr.
Ste. 100
Plano, Texas 75093

September 3, 2024

Re: K242069

Trade/Device Name: Eminent Spine Scoliosis Deformity Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: August 15, 2024
Received: August 16, 2024

Dear Stephen Courtney:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Eileen Digitally signed by
Eileen Cadell -S
Cadell -S Date: 2024.09.03
11:13:15 -04'00'

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K242069

Device Name
Eminent Spine Scoliosis Deformity Pedicle Screw System

Indications for Use (Describe)

The Eminent Spine Scoliosis Deformity Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system (T1-S2/Ilium). The system is intended for posterior, pedicle fixation in skeletally mature patients for the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (DDD) (defined as back pain with discogenic origin with degeneration of the disc confirmed by history and radiographophic studies), severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudoarthrosis and failed previous fusion.

When used for fixation to the ilium, the offset connectors of the Eminent System must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Eminent Spinal Scoliosis Deformity Pedicle Screw System is indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Eminent Spine Deformity Pedicle System is intended to treat pediatric patients diagnosed with: spondylolisthesis / spondylolysis, fracture caused by tumor and/or trauma, pseudoarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitted By: Eminent Spine, LLC
2004 Ventura Dr. Suite #100
Plano, TX 75093

Date: 08/20/2024

Contact Person: Stephen Courtney, CEO, Eminent Spine
Contact Telephone: (972) 499-3593
Contact Fax: N/A

Device Trade Name: Eminent Spine Scoliosis Deformity Pedicle Screw System
Common Name: Pedicle Screw Spinal System
Device Classification Name: Orthosis, spinal pedicle fixation
Device Classification: Class II - 21 CFR 888.3070 - Thoracolumbarsacral Pedicle Screw System
Reviewing Panel: Orthopedic
Product Code: NKB
Primary Predicate Device: Eminent Spine Diamondback Pedicle Screw System (K100377)
Additional Predicate Devices: NEXXT Spine Inertia® Pedicle and Deformity Correxxion System (K153453)

Device Description:

The Eminent Spine Scoliosis Deformity Pedicle System consists of rods, polyaxial screws with set caps, and cross connectors with locking screws. Additionally, the system consists of rod connectors and iliac bolts with their respective locking screws. Rods are 5.5mm in diameter and are available either straight or pre-contoured. Straight and pre-contoured rods are each offered in lengths ranging from 40mm to 600mm in various increments. Cannulated polyaxial screws are available in 6.0mm to 12.5mm diameters and in lengths ranging from 40mm to 110mm in 5mm increments. Set caps are used to fasten the rod and screw. Cross connectors are available in 3 length ranges: 32mm-42mm, 42mm-58mm, and 58mm-74mm. Cross connectors lock screws are used to fasten the cross connector together and fasten across the rods. Rod connectors are offered in 3 types and the iliac bolts are offered in 1 type. All of the components are available in a variety of sizes to match more closely to the patient's anatomy. All components are made from titanium alloy per ASTM F136.

Indications for Use:

The Eminent Spine Scoliosis Deformity Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system (T1-S2/Ilium). The system is intended for posterior, pedicle fixation in skeletally mature patients for the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (DDD) (defined as back pain with discogenic origin with degeneration of the disc confirmed by history and radiographophic studies), severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudoarthrosis and failed previous fusion.

When used for fixation to the ilium, the offset connectors of the Eminent System must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Eminent Spinal Scoliosis Deformity Pedicle Screw System is indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Eminent Spine Deformity Pedicle System is intended to treat pediatric patients diagnosed with: spondylolisthesis / spondylolysis, fracture caused by tumor and/or trauma, pseudoarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.



Technological Characteristics Comparison

The technological design features of the subject Eminent Spine Scoliosis Deformity Pedicle Screw System is substantially equivalent to the predicate devices (K100377 and K153453). The technological design features of the subject implants were compared to the predicates in intended use, indications for use, design, function, and technology and it was demonstrated that they are substantially equivalent

Mechanical Testing:

Substantial equivalence is supported by the results of mechanical testing. Construct tests were conducted according to ASTM F1717, including static torsion, static compression bending, and dynamic compression bending. Rod connector axial and torsional grip tests were conducted according to ASTM F1789. Results support the substantial equivalence of the subject device compared to predicate devices.

Conclusion:

Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence for its intended use.