May 16, 2023

Eminent Spine, LLC
℅ Jennifer Palinchik
President
Jalex Medical
27865 Clemens Rd, Suite 3
Westlake, Ohio 44145

Re: K230219
Trade/Device Name: Eminent Spine 3D Lumbar Interbody Fusion Systems
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 14, 2023
Received: March 14, 2023

Dear Jennifer Palinchik:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Katherine D.
Kavlock -S

for

Brent Showalter, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230219

Device Name
Eminent Spine 3D Lumbar Interbody Fusion Systems

Indications for Use *(Describe)*
The Eminent Spine 3D Lumbar Interbody Fusion Systems (PLIF, TLIF, and ALIF) are indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and autograft to facilitate fusion. Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

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: 05/15/2023

Contact Person: Jennifer Palinchik, President, JALEX Medical
Contact Telephone: (440) 935-3282
Contact Fax: (440) 933-7839

Device Trade Name: Eminent Spine 3D Lumbar Interbody Fusion Systems
Common Name: Intervertebral Body Fusion Device
Device Classification Name: Intervertebral Body Fusion Device with Bone Graft, Lumbar
Device Classification: Class II
Reviewing Panel: Orthopedic
Product Code: MAX
Primary Predicate Device: Eminent Spine Interbody Fusion System (K090064)
Additional Predicate Devices: Eminent Spine 3D Cervical Interbody Fusion System (K212701)
CancelleX Porous Titanium Lumbar Interbody Device (K190364)

Device Description:

The Eminent Spine 3D Lumbar Interbody Fusion Systems are intervertebral body fusion systems used in the spine to replace a collapsed, damaged, or unstable disc. The 3D Lumbar Interbody Fusion Systems (PLIF, TLIF, and ALIF) are comprised of various sizes and configurations to accommodate individual patient anatomy. The configurations are designed to provide the surgeon with different surgical approach options, and packed with autogenous bone graft to facilitate fusion. Serrations on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebral bodies to aid in expulsion resistance. The device is intended to provide mechanical support to the implanted level until biologic fusion is achieved.

Indications for Use:

The Eminent Spine 3D Lumbar Interbody Fusion Systems (PLIF, TLIF, and ALIF) are indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and autograft to facilitate fusion. Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

Summary of Technological Characteristics:

The Eminent Spine 3D Lumbar Interbody Fusion Systems and the predicates have the same intended use and fundamental scientific technology. All devices compare similarly in:

- Design features
- Intended use
- Materials
- Dimensions
- Function

Table 1: Dimensions and Technological Characteristics Comparison

Item	Eminent Spine 3D Lumbar Interbody Fusion Systems	Eminent Spine Interbody Fusion System (K090064)	Eminent Spine 3D Cervical Interbody Fusion System (K212701)	Comparison
Classification Name	Intervertebral Body Fusion Device	Intervertebral Body Fusion Device	Intervertebral Body Fusion Device	Equivalent
Regulation	888.3080	888.3080	888.3080	Equivalent
Product Code	MAX	MAX, MQP, ODP	ODP	Intervertebral body fusion device code equivalent to primary predicate
Indications for Use	The Eminent Spine 3D Lumbar Interbody Fusion Systems (PLIF, TLIF, and ALIF) are indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and autograft to facilitate fusion.	The Eminent Spine Interbody Fusion System (Sidewinder, Python and Cottonmouth) is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation	The Eminent Spine 3D Cervical Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.	Intervertebral body fusion indications equivalent to primary predicate

	Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.	and autograft to facilitate fusion. The Eminent Spine System of implants is indicated for use to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma/fracture. The implant is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation and autograft or allograft bone. These devices are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.		
Description	The Eminent Spine 3D Lumbar Interbody Fusion Systems are intervertebral body fusion systems used in the spine to replace a collapsed, damaged, or unstable disc. The 3D Lumbar Interbody Fusion Systems (PLIF, TLIF, and ALIF) are comprised of various sizes and configurations to accommodate individual patient anatomy. The configurations are designed to provide the surgeon with different surgical approach options, and packed with autogenous bone graft to facilitate fusion. Serrations on the superior and inferior	The Eminent Spine Interbody Fusion System is comprised of various sizes and configuration to accommodate individual patient anatomy. The configurations are designed to provide the surgeon with different surgical approach options.	The Eminent Spine 3D Cervical Interbody Fusion System is comprised of various sizes and configuration to accommodate individual patient anatomy. The device is a hollow rectangular shaped block, which is available in a parallel or lordotic configurations. The device is hollow to allow for placement of bone graft. There are teeth on the superior and inferior surfaces of the device to inhibit movement of the device.	Equivalent to primary predicate

	surfaces of each device grip the endplates of the adjacent vertebral bodies to aid in expulsion resistance. The device is intended to provide mechanical support to the implanted level until biologic fusion is achieved.			
Footprints	PLIF: 22-31 mm x 9-12 mm TLIF: 28-34 mm x 11 mm ALIF: 32-42 mm x 21-28 mm	Python (PLIF): 22-31 mm x 9-12 mm Sidewinder (TLIF): 28-31 mm x 11 mm Cottonmouth (ALIF): 32-42 mm x 21-28 mm	14x12 mm, 15x13 mm, 17x12 mm, 17x14 mm, 19x16 mm	Equivalent to primary predicate
Heights	PLIF: 6-18 mm TLIF: 6-18 mm ALIF: 10-20 mm	Python (PLIF): 6-18 mm Sidewinder (TLIF): 6-18 mm Cottonmouth (ALIF): 10-20 mm	5-12 mm	Equivalent to primary predicate
Lordotic angle	6°, 12°, 18°, 24°, 30° (depending on model)	6°, 12°, 18°, 24°, 30° (depending on model)	0°, 6°	Equivalent to primary predicate
Material	Ti-6Al-4V per ASTM F3001	PEEK Optima LT1 and Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V per ASTM F3001	Equivalent to additional predicate

Mechanical Testing:

Substantial equivalence is supported by the results of mechanical testing, including static axial compression, static axial compression-shear, dynamic axial compression, dynamic axial compression-shear per ASTM F2077, subsidence per ASTM F2267, and expulsion. Results support that the subject device performs as well as or better than the chosen acceptance criteria.

Conclusion:

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