February 6, 2023

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

Re: K212701
Trade/Device Name: Eminent Spine 3D Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: January 25, 2023
Received: January 25, 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)*

K212701

Device Name
Eminent Spine 3D Cervical Interbody Fusion System

Indications for Use *(Describe)*

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.

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.

510(k) Summary

Submitted By:	Eminent Spine 2004 Ventura Dr. Suite #100 Plano, TX 75093
Date:	01/25/2023
Contact Person:	Jennifer Palinchik, President
Contact Telephone:	(440) 935-3282
Contact Fax:	(440) 933-7839
Device Trade Name:	Eminent Spine 3D Cervical Interbody Fusion System
Common Name:	Intervertebral Body Fusion Device
Device Classification Name:	Intervertebral Body Fusion Device with Bone Graft, Cervical
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Product Code:	ODP
Primary Predicate Device:	Eminent Spine Copperhead Interbody Fusion System (K090064) The primary predicate device has never been subject to a recall.
Reference Predicate Device:	Tailored-C Cervical Interbody Fusion System (200458) The reference predicate devices have never been subject to a recall.

Device Description:

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.

This submission is to introduce additively manufactured versions of the implants to the existing Eminent Spine Copperhead Interbody Fusion System.

Indications for Use:

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.

Summary of Technological Characteristics:

The Eminent Spine 3D Cervical Interbody Fusion System 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 Cervical Interbody Fusion System (Subject Device)	Eminent Spine Interbody Fusion System (K090064)	Tailored-C Cervical Interbody Fusion System (200458)	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	ODP	ODP	ODP	Equivalent
Indications for Use	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	The Eminent Spine Interbody Fusion System (Copperhead) 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.	The Tailored-C Cervical Interbody Fusion Devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Tailored-C Cervical implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at one disc level (C2-T1) using autograft bone. Tailored-C Cervical implants are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.	Equivalent

Item	Eminent Spine 3D Cervical Interbody Fusion System (Subject Device)	Eminent Spine Interbody Fusion System (K090064)	Tailored-C Cervical Interbody Fusion System (200458)	Comparison
	with an intervertebral cage.			
Description	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. Copperhead 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.	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 Tailored-C Cervical Interbody Fusion System is an intervertebral spinal fixation system comprised of additively manufactured cervical interbody spacers. They are designed to provide mechanical support to the cervical spine while arthrodesis occurs. The implant has a partially porous construction and an open architecture with a large variety of footprints and lordosis angles to optimize patient fit. The footprints are offered at 11x13mm, 12x14mm, 14x16mm, 16x18mm, and 17x19mm. The lordosis is offered at 0˚, 4˚, and 7˚. The height ranges from 5mm to 12mm in 1mm increments.	Equivalent
Footprints	14x12 mm, 15x13 mm, 17x12 mm, 17x14 mm, 19x16 mm	14x12 mm, 15x13 mm, 17x12 mm, 17x14 mm, 19x16 mm	11x13mm, 12x14mm, 14x16mm, 16x18mm, 17x19mm	Equivalent
Heights	5-12 mm	5-12 mm	5-12 mm	Equivalent
Lordotic angle	0°, 6°	0°, 6°	0°, 4°, 7°	Equivalent
Material	Ti-6Al-4V ELI per ASTM F3001	PEEK Optima LT1	Ti-6Al-4V per ASTM F3001	Equivalent

Mechanical Testing:

Substantial equivalence is supported by the results of mechanical testing, including:

- Static and dynamic compression bending per ASTM 2077
- Static and dynamic torsion per ASTM 2077
- Expulsion

- Subsidence per ASTM F2267

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.