October 17, 2022

Eminent Spine
% Daniel Johnson
Engineer
Jalex Medical
27865 Clemens Rd
Suite 3
Westlake, Ohio 44145

Re: K221936
Trade/Device Name: Standalone ALIF Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: September 8, 2022
Received: September 9, 2022

Dear Daniel Johnson:

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,

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)*

K221936

Device Name

Standalone ALIF Interbody Fusion System

Indications for Use *(Describe)*

The Eminent Spine Standalone ALIF Interbody Fusion System 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 Eminent Spine Standalone ALIF Interbody Fusion System is a stand-alone interbody fusion device intended to be used with screws which accompany the spacers for fixation. Hyperlordotic implants (≥25˚ lordosis) are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). The device is intended for use at either one or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I Spondylolisthesis or retrolisthesis. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. The device is designed for use with autograft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion. Patients should have at least six (6) months 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Date: 06/29/2022

Contact Person: Daniel Johnson, Engineer
Contact Telephone: (216) 333-2127
Contact Fax: (440) 933-7839

Device Trade Name: Standalone ALIF Interbody Fusion System
Common Name: Intervertebral Body Fusion Device
Device Classification Name: Intervertebral Body Fusion Device with Integrated Fixation, Lumbar
Device Classification: Class II
Reviewing Panel: Orthopedic
Product Code: OVD
Primary Predicate Device: Globus HEDRON Lumbar Spacers (K191391)
The primary predicate device has never been subject to a recall.
Reference Predicate Device: Eminent Cervical Stand-Alone System (K212853)
The reference predicate devices have never been subject to a recall.

Device Description:

The Standalone ALIF devices are inserted through an anterior lumbar approach 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, while screws are inserted through the anterior face of the implant for bone fixation. The device is intended to provide mechanical support to the implanted level until biologic fusion is achieved.

The cages are made from medical grade polyetheretherketone (PEEK) per ASTM F2026 with tantalum per ASTM F560 pins, from titanium alloy Ti-6Al-4V ELI per ASTM F136, or from additively manufactured Ti-6Al-4V per ASTM F3001. The integrated fixation screws and screw anti-backout plate are manufactured from Ti-6Al-4V ELI per ASTM F136.

Indications for Use:

The Eminent Spine Standalone ALIF Interbody Fusion System 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 Eminent Spine Standalone ALIF Interbody Fusion System is a stand-alone interbody fusion device intended to be used with screws which accompany the spacers for fixation. Hyperlordotic implants (>=25° lordosis) are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). The device is intended for use at either one or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I Spondylolisthesis or retrolisthesis. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. The device is designed for use with autograft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Summary of Technological Characteristics:

The Eminent Spine Standalone ALIF 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

Mechanical Testing:

Substantial equivalence is supported by the results of mechanical testing in the following test modes:

- Static compression
- Static compression-shear
- Static torsion
- Subsidence
- Expulsion
- Dynamic compression
- Dynamic compression-shear
- Dynamic torsion

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.