SpineEX Inc.
% Ms. Meredith May
Vice President
Empirical Consulting LLC
4628 Northpark Drive
Colorado Springs, Colorado 80918

October 5, 2018

Re: K181531
Trade/Device Name: SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: September 17, 2018
Received: September 20, 2018

Dear Ms. May:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181531

Device Name
SpineEX Sagittae (R) Lateral Lumbar Interbody Fusion Devices

Indications for Use *(Describe)*

The SpineEX Sagittae® Lateral Lumber Interbody Fusion Devices are indicated for interbody fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment. Supplemental fixation is required with SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices. Additionally, the SpineEX devices are intended to be used with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine (e.g. posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). 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.

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

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5. 510(K) SUMMARY

Submitter's Name:	SpineEX Inc.
Submitter's Address:	4046 Clipper Court Fremont, CA 94538
Submitter's Telephone:	(510) 573-6165
Company Contact Person:	Andrew Rogers
Contact Person:	Meredith Lee May MS, RAC Empirical Consulting LLC 719-337-7579 MMAy@EmpiricalConsulting.com
Date Summary was Prepared:	08 June 2018
Trade or Proprietary Name:	SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The SpineEX Sagittae® Lateral Lumber Interbody Fusion Devices are manufactured out of medical grade Ti-6Al-4V (Grade 5) and Ti-6A-4V (ELI) alloy that conforms to ASTM F1472 and ASTM F136 respectively.

INDICATIONS FOR USE

The SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices are indicated for interbody fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment. Supplemental fixation is required with SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices. Additionally, the SpineEX devices are intended to be used with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine (e.g. posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for use
- Materials of manufacture
- Structural support mechanism
- Principles of operation

Table 5-1: Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K123752	AccuLiF®	CoAlign Innovation	Primary
K123231	Caliber-L	Globus	Additional
K133813	FLXfit IBFD	Expanding Orthopedics	Additional
K123045	Brigade® Hyperlorditic System	NuVasive®	Additional
K073144	Timberline IBFD	Lanx	Additional

PERFORMANCE DATA

The SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices have been tested in the following test modes:

- Static axial compression per ASTM 2077
- Static compressive shear per ASTM 2077
- Dynamic axial compression per ASTM 2077
- Dynamic compressive shear per ASTM 2077
- Subsidence per ASTM F2267

The results of this non-clinical testing show that the strength of the SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices are sufficient for their intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices are substantially equivalent to the predicate devices.