April 30, 2020

SpineEX, Inc.
Mr. Nathan Wright
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K200816
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: March 27, 2020
Received: March 30, 2020

Dear Mr. Wright:

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.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200816

Device Name
SpineEX Sagittae® Lateral Lumbar Interbody Fusion System

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.

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510(K) SUMMARY

Submitter's Name:	SpineEX, Inc.
Submitter's Address:	4046 Clipper Court Fremont, CA 94538
Submitter's Telephone:	510-573-6165
Contact Person:	Nathan Wright MS Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	27-Mar-2020
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.

The indications for use for the SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices are identical to the previously cleared SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices under K181531 and K190193.

TECHNICAL 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**
K181531, K190193	SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices	SpineEX, Inc.	Primary

PERFORMANCE TESTING SUMMARY

Minor design modifications to the SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices cleared under K181531 and K190193 have been evaluated mechanically through performance testing per ASTM F2077.

CONCLUSION

The subject modified SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices are very similar to previously cleared SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices. The subject has identical uses, indications, technological characteristics, and principles of operation as the predicate device. The modifications raise no new types of safety or efficacy questions. The overall technology characteristics lead to the conclusion that SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices is substantially equivalent to the predicate device.