October 2, 2020

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

Re: K202190
Trade/Device Name: Oculus™-SA Lumbar Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: August 4, 2020
Received: August 5, 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.
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 on last page.

510(k) Number *(if known)*
K202190

Device Name
Oculus™-SA Lumbar Cage System

Indications for Use *(Describe)*

The Oculus-SA Lumbar Cage System is intended for spinal fusion procedures at one level (L2 to S1) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the non-cervical spine. Implants are intended to be implanted via an open, anterior approach and packed with bone graft. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to a Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These implants are used to facilitate fusion in the lumbar spine and are placed via an anterior (ALIF) approach. Hyperlordotic implants (those with a lordotic angle greater than or equal to 20°) are indicated for use with a supplemental spinal fixation system that has been cleared by the FDA. The Oculus-SA Lumbar Cage System implants with a lordotic angle less than 20°, when used with the internal fixation screws, do not require use of 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.

510(K) SUMMARY

Submitter's Name:	Neurostructures, Inc.
Submitter's Address:	199 Technology Drive, Suite 110 Irvine, CA 92618
Submitter's Telephone:	800-352-6103
Contact Person:	Nathan Wright MS Empirical Testing Corp 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	August 3, 2020
Trade or Proprietary Name:	Oculus™-SA Lumbar Cage System
Common or Usual Name:	Intervertebral Fusion Device With Integrated Fixation, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	OVD
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Oculus-SA Lumbar Cage System is a stand-alone spinal intervertebral fusion device made from medical grade PEEK (polyetheretherketone) as per ASTM F2026 or Ti 6Al-4V ELI Alloy as per ASTM F136. It is provided in a variety of footprints, styles, and sizes to accommodate various patient anatomies. The PEEK cages have one radiographic marker pin made from tantalum, per ASTM F560. The implants incorporate integrated anterior screw holes to allow for placement of titanium alloy (per ASTM F136) screws. The Oculus-SA Lumbar Cage System is offered in either a three screw or four screw configuration for anterior lumbar interbody fusion procedures. Titanium alloy locking mechanisms secure the screws in place. The Oculus-SA Lumbar Cage System implants and instruments are provided non-sterile and will require sterilization prior to each use.

INDICATIONS FOR USE

The Oculus-SA Lumbar Cage System is intended for spinal fusion procedures at one level (L2 to S1) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the non-cervical spine. Implants are intended to be implanted via an open, anterior approach and packed with bone graft. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to a Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These implants are used to facilitate fusion in the lumbar spine and are placed via an anterior (ALIF) approach. Hyperlordotic implants (those with a lordotic angle greater than or equal to 20°) are indicated for use with a supplemental spinal fixation system that has been cleared by the FDA. The Oculus-SA Lumbar

Cage System implants with a lordotic angle less than 20°, when used with the internal fixation screws, do not require use of supplemental fixation.

The indications for use for the Oculus™-SA Lumbar Cage System is similar to that of the predicates listed in Table 5-1.

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:

- Principles of Operation
- Indications for Use
- Implant Materials
- Implant Sizes
- Surgical Approach
- Manufacturing

Table 5-1 Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K182195	Arco™-SA Lumbar Cage System	NeuroStructures, Inc.	Primary
K173082	Arco™-SA Lumbar Cage System	NeuroStructures, Inc.	Additional
K180814	M3 Stand-Alone ALIF	CoreLink, LLC	Additional
K161129	PILLAR® SA PTC	Orthofix Inc.	Additional
K130445	Vault ALIF System	Spinal USA	Additional
K142060	Transom Anterior Cervical Plate	NeuroStructures, Inc.	Reference

PERFORMANCE DATA

The Oculus™-SA Lumbar Cage System has been tested in the following test modes:

- Static axial compression per ASTM F2077-18
- Static compressive shear per ASTM F2077-18
- Dynamic axial compression per ASTM F2077-18
- Dynamic compressive shear per ASTM F2077-18
- Static subsidence per ASTM F2267-04 (2018)

The results of this non-clinical testing show that the strength of the Oculus™-SA Lumbar Cage System is sufficient for its 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 Oculus™-SA Lumbar Cage System is substantially equivalent to the predicate device.