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

November 9, 2018

Re: K182195
Trade/Device Name: Arco™-SA Lumbar Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: October 22, 2018
Received: October 23, 2018

Dear Meredith 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,

David Hwang -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)*
K182195

Device Name
Arco™-SA Lumbar Cage System

Indications for Use *(Describe)*
The Arco™-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) on the non-cervical spine. Implants are intended to be implanted via an open, anterior approach and packed with autograft and/or allograft comprised of cancellous and/or corticocancellous 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 fixation system cleared by the FDA. The Arco™-SA Lumbar Cage System interbody 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.

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."

5. 510(K) SUMMARY

Submitter's Name	Neurostructures, Inc.
Submitter's Address	16 Technology Drive, Suite 165 Irvine, CA 92618
Company Contact Person	Kathleen Wong kw@neurostructures.com 949.370.4497
Contact Person	Meredith L. May MS, RAC Empirical Consulting 719-337-7579 MMay@EmpiricalConsulting.com
Date Summary was Prepared	29-May-18
Trade or Proprietary Name	Arco™-SA Lumbar Cage System
Common or Usual Name	Intervertebral Fusion Device With Integrated Fixation, Lumbar
Classification	Class II per 21 CFR §888.3050 Device Classification
Product Code	OVD
Classification Panel	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Arco™-SA ALIF System is an intervertebral fusion device made from titanium per ASTM F136 with TECOTEX® surface from TECOMET, Inc. or medical grade PEEK per ASTM F2026 with tantalum markers per ASTM F560. The subject device implant cages are offered in a variety of footprints and sizes to accommodate various patient anatomies. The Arco™-SA ALIF System is offered in heights of 12-22mm, widths of 28-43mm, and lengths of 24-32mm. The subject device implant screws are offered in Ø5.0-6.0mm diameters and lengths ranging 20-35mm. The subject device implant is offered with a lordosis of 7- 30°. The purpose of this submission is to add larger footprint options and add the titanium implants to the previously cleared system

INDICATIONS FOR USE

The Arco™-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 autograft and/or allograft comprised of cancellous and/or corticocancellous 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 levels(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 Arco™-SA Lumbar Cage System interbody implants with a lordotic angle less than 20°, when used with the internal fixation screws, do not require use of 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:

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

Table 5-1: Predicate

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K173082	Arco™ SA Lumbar Cage System	NeuroStructures	Primary
K161129	PILLAR® SA PTC	Orthofix, Inc.	Additional
K172064	Ti-Diagon Oblique TLIF	Camber Spine Technologies	Reference

PERFORMANCE DATA

A comparison of the previously cleared device material and the subject device material was completed *in lieu* of mechanical testing.

CONCLUSION

The overall technology and material characteristics lead to the conclusion that the Arco™-SA Lumbar Cage System is substantially equivalent to the predicate device.