



March 29, 2018

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

Re: K173082

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: February 21, 2018
Received: February 22, 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173082

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) 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 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.

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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	15 February 2018
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 §888.3080 Device Classification
Product Code	OVD
Classification Panel	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Arco™-SA Lumbar Cage System is an intervertebral fusion device made from medical grade PEEK per ASTM F2026, titanium per ASTM F136, and 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 Lumbar Cage System is offered in heights of 12-22mm, widths of 28- 38mm, and lengths of 24-29mm. 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°.

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 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.

The indications for use for the Arco™-SA Lumbar Cage System is similar to that of the Table 5-1: Predicate Devices.

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 Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K161230	Lumbar Interbody Implants	NuVasive®	Primary
K131276	SYNFIX Lateral/SynFix-LR System	Synthes	Additional
K133967	IBFD	Aurora Spine	Additional
K132421	Implant Systems	Aesculap®	Additional
K131122	Stand-Alone ALIF System	Renovis	Additional
K150643	MIDLINE II™	Centinel Spine	Additional
K120966	Lumbar System	Depuy	Additional
K171914	Cortina™ Lumbar Cage System	NeuroStructures	Reference

PERFORMANCE DATA

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

- Static axial compression per ASTM F2077-11
- Static compressive shear per ASTM F2077-11
- Dynamic axial compression per ASTM F2077-11
- Dynamic compressive shear per ASTM F2077-11
- Static subsidence per ASTM F2267-04
- Static expulsion per ASTM DRAFT F-04.25.02.02

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