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

November 25, 2019

Re: K192248
Trade/Device Name: Cortina™ [MAX] Lumbar Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: October 28, 2019
Received: October 29, 2019

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/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,

for
Brent Showalter, Ph.D.
Assistant Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020

Indications for Use

510(k) Number *(if known)*
K192248

Device Name
Cortina™ [MAX] Lumbar Cage System

Indications for Use *(Describe)*

The Cortina™ [MAX] Lumbar Cage System is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion combined with supplemental fixation. The interior of the Cortina™ [MAX] Lumbar Cage System should be packed with autogenous bone graft (i.e. autograft). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

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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5. 510(K) SUMMARY

Submitter's Name	Neurostructures, Inc.
Submitter's Address	199 Technology Drive, Suite 1110 Irvine, CA 92618
Submitter's Telephone	800-352-6103
Company Contact Person	Moti Altarac
Contact Person	Meredith Lee May MS, RAC Empirical Consulting 719-337-7579 Mmay@EmpiricalConsulting.com
Date Summary was Prepared	12-Aug-19
Trade or Proprietary Name	Cortina™ [MAX] Lumbar Cage System
Common or Usual Name	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification	Class II per 21 CFR §888.3080 Device Classification
Product Code	MAX
Classification Panel	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The Cortina™ [MAX] Lumbar Cage System is an intervertebral fusion device made from medical grade PEEK with tantalum markers manufactured from EVONIK PEEK as described in MAF-1922 with the submissions of the predicate Cortina [MAX] (K171914 and K180431) or medical grade titanium per ASTM F136 with a TECOTEX® surface coating. The subject device is offered in a variety of styles and sizes to accommodate various patient anatomies. This submission is intended to add the titanium implants and expand the size offering to include larger footprints.

INDICATIONS FOR USE

The Cortina™ [MAX] Lumbar Cage System is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion combined with supplemental fixation. The interior of the Cortina™ [MAX] Lumbar Cage System should be packed with autogenous bone graft (i.e. autograft). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

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**
K171914/ K180431	Cortina™ [MAX] Lumbar Cage System	NeuroStructures	Primary
K172064	Ti-Diagon Oblique TLIF	Camber Spine Technologies	Additional
K173080	IVA CAGE Ti (ACIF, PLIF, TLIF, DLIF and ALIF)	HUVEXEL	Additional
K172320	Cavetto® Cervical Cage System	NeuroStructures, Inc.	Reference
K142041	PorOsteon Phusion Metal Cervical Cage	PorOsteon, Inc.	Reference

PERFORMANCE DATA

The subject devices that are manufactured from titanium require no additional testing, for they are identical in form, shape, and function to the previously cleared devices manufactured from PEEK (K171914/K180431). Titanium material produces implants with a higher yield load and stiffness when the shape is identical, therefore no testing is required.

The subject devices that are manufactured from PEEK present no new worst case to what was to what was previously cleared (K171914/K180431). The addition of the longer (36-42 mm) PLIF implants does not create a new mechanical worst-case for the system as opposed to the 20x9x7mm PLIF tested for the previous clearance , therefore no additional testing is required for the additional length in the line extension.

The DLIF does not need to be tested as a new worst-case for the system, as the design and footprint do not represent a new worst-case for either static or dynamic mechanical testing. The smallest DLIF is significantly larger than what was previously tested for clearance. Additionally, the design of the DLIF is considerably simpler than the tested PLIF and has fewer areas of concern for mechanical integrity.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Cavetto® [MAX] Cervical Cage System is substantially equivalent to the predicate device.