March 22, 2018

NeuroStructures, Inc.
Kathleen Wong
Director of RA & QA
16 Technology Drive, Suite 165
Irvine, California 92618

Re: K180431
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: February 15, 2018
Received: February 16, 2018

Dear Ms. Wong:

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,

Mark N. Melkerson -S

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)*
K180431

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 lo S 1 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 confim1ed 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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K180431 - 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	Kathleen Wong kw@neurostructures.com 949.370.4497
Date Summary was Prepared	15 February 2018
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 §888.3050 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 titanium markers. The subject device is offered in a variety of styles and sizes to accommodate various patient anatomies.

This 510(k) is submitted only for the purposes of changing the name of the Cortina™ (K171914) to the Cortina™ [MAX]. The two devices are otherwise identical, and no changes whatsoever have been made to the Cortina™ (K171914).

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.

The indications for use for the Cortina™ [MAX] Lumbar Cage System is identical to that of the primary predicate and similar to that of the additional predicates noted in Table 5-1: Predicate Devices.

TECHNOLOGICAL CHARACTERISTICS

The subject and primary predicate device are identical in technological characteristics. The subject and additional 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 primary predicate:

- 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	Cortina Lumbar Cage System	NeuroStructures	Primary

PERFORMANCE DATA

The Cortina™ [MAX] Lumbar Cage System has been tested in the following test modes:

- Static axial compression per ASTM F2077-11
- Dynamic axial compression 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 Cortina™ [MAX] 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 Cortina™ [MAX] Lumbar Cage System is substantially equivalent to the predicate devices.