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

November 8, 2018

Re: K181590
Trade/Device Name: Neurostructures Cavetto® [MAX] Cervical Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: October 10, 2018
Received: October 12, 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. 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)*
K181590

Device Name
Neurostructures Cavetto® [MAX] Cervical Cage System

Indications for Use *(Describe)*
The Neurostructures Cavetto® [MAX] Cervical Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Neurostructures Cavetto® [MAX] Cervical Cage System is to be used with autogenous or allogenic bone graft composed of cancellous and/or corticocancellous bone graft and placed via an open, anterior approach. The Neurostructures Cavetto® [MAX] Cervical Cage System is intended to be used with 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.

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5. 510(K) SUMMARY

Submitter's Name	Neurostructures, Inc.
Submitter's Address	199 Technology Drive, Suite 110 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	30 May 2018
Trade or Proprietary Name	Neurostructures Cavetto® [MAX] Cervical Cage System
Common or Usual Name	Intervertebral Fusion Device With Bone Graft, Cervical
Classification	Class II per 21 CFR §888.3080
Product Code	ODP
Classification Panel	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Cavetto® [MAX] Cervical Cage System is an intervertebral fusion device made from medical grade titanium per ASTM F136. The subject device is offered in a variety of footprints, styles, and sizes to accommodate various patient anatomies. The Cavetto® [MAX] Cervical Cage System is offered in parallel and lordotic styles in heights of 4-10mm, widths of 13-19mm, and lengths of 11-16mm.

INDICATIONS FOR USE

The Neurostructures Cavetto® [MAX] Cervical Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Neurostructures Cavetto® [MAX] Cervical Cage System is to be used with autogenous or allogenic bone graft composed of cancellous and/or corticocancellous bone graft and placed via an open, anterior approach. The Neurostructures Cavetto® [MAX] Cervical Cage System is intended to be used with supplemental fixation.

The indications for use for the Cavetto® [MAX] Cervical Cage System is similar to that of the predicates in Table 5-1: Predicate Devices.

TECHNOLOGICAL CHARACTERISTICS

The Cavetto® [MAX] Cervical Cage System 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 similar between the subject and predicates:

- Indications for use
- Principles of operations
- Implant material
- Sterility
- Surgical approach
- Structural support mechanism

Table 5-1: Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K172320	Cavetto® Cervical Cage System	NeuroStructures	Primary
K172064	Ti-Diagon Oblique TLIF	Camber Spine Technologies	Reference
K142041	PorOsteon Phusion Metal Cervical Cage	PorOsteon, Inc.	Reference

PERFORMANCE DATA

An engineering comparison of the material used to manufacture the previously cleared device and the subject device material was completed in lieu of mechanical testing, showing that the subject device is mechanically substantially equivalent to the primary predicate device. Bacterial endotoxin (LAL) testing was conducted and met endotoxin limit specifications.

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.