September 3, 2020

NeuroStructures, Inc.
% Nathan Wright, M.S.
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K201769
Trade/Device Name: 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: June 26, 2020
Received: June 29, 2020

Dear Mr. Wright:

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
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K201769

Device Name
Cavetto® [MAX] Cervical Cage System

Indications for Use *(Describe)*
The 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 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 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.

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510(K) SUMMARY

Submitter's Name	NeuroStructures, Inc.
Submitter's Address	199 Technology Drive, Suite 110 Irvine, CA 92618
Contact Person	Nathan Wright MS Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared	September 1, 2020
Trade or Proprietary Name	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 PEEK per ASTM F2026 with tantalum markers per ASTM F560. 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.

This 510(k) is submitted only for the purposes of changing the name of the Cavetto® Cervical Cage System (K172320) to the Cavetto® [MAX] Cervical Cage System. The two devices are otherwise identical, and no changes whatsoever have been made to the Cavetto® Cervical Cage System (K172320).

INDICATIONS FOR USE

The 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 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 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 identical to that of the primary predicate.

TECHNOLOGICAL CHARACTERISTICS

The Cavetto® [MAX] Cervical Cage System and predicate device have identical technological characteristics.

Specifically, the following characteristics are identical between the subject and predicate:

- Indications for use
- Principles of operations
- Implant material PEEK
- Implant material tantalum
- Implant height
- Implant width
- Implant length
- Implant lordosis
- Surgical approach
- Structural support mechanism
- Implant bone graft volume

Table 5-1: Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K172320	Cavetto® Cervical Cage System	NeuroStructures	Primary
K142041	PorOsteon Phusion Metal Cervical Cage	PorOsteon	Additional

PERFORMANCE DATA

The devices in the Cavetto® [MAX] Cervical Cage System did not introduce a new worst-case construct compared to the predicate in terms of mechanical performance. Thus, testing previously conducted on the predicate was leveraged for this submission. This testing included:

- Static axial compression per ASTM F2077
- Static torsion per ASTM F2077
- Dynamic axial compression per ASTM F2077
- Dynamic torsion per ASTM F2077
- Static subsidence per ASTM F2267
- Static expulsion

The results of this non-clinical testing show that the strength of the Cavetto® [MAX] Cervical 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 Cavetto® [MAX] Cervical Cage System is substantially equivalent to the predicate device.