September 24, 2020

NeuroStructures, Inc.
℅ Mr. Nathan Wright
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K200115
Trade/Device Name: Cavetto®-SA Cervical Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: August 26, 2020
Received: August 27, 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,

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)*
K200115

Device Name
Cavetto(R)-SA Cervical Cage System

Indications for Use *(Describe)*
The Cavetto®-SA Cervical Cage System is intended for spinal fusion procedures at one level (C2 to T1) in skeletally mature patients with degenerative disc disease (defined as pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are intended to be implanted via an open, anterior approach and packed with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. This cervical device is to be used in patients who have had six weeks of non-operative treatment. The Cavetto®-SA Cervical Cage System should be used with the provided bone screws and requires no additional supplementary fixation systems.

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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K200115 - 510(K) SUMMARY

Submitter's Name:	NeuroStructures, Inc.
Submitter's Address:	199 Technology Drive, Suite 110 Irvine, CA 92618
Submitter's Telephone:	800-352-6103
Company Contact Person	Moti Altarac
Contact Person:	Nathan Wright Empirical Testing Corp. nwright@empiricaltech.com 719-337-7579
Date Summary was Prepared:	January 15, 2020
Trade or Proprietary Name:	Cavetto®-SA Cervical Cage System
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Cervical Intervertebral Fusion Device With Integrated Fixation, Cervical
Classification:	Class II per 21 CFR §888.3080
Product Code:	OVE
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Cavetto®-SA 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.

INDICATIONS FOR USE

The Cavetto®-SA Cervical Cage System is intended for spinal fusion procedures at one level (C2 to T1) in skeletally mature patients with degenerative disc disease (defined as pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are intended to be implanted via an open, anterior approach and packed with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. This cervical device is to be used in patients who have had six weeks of non-operative treatment. The Cavetto®-SA Cervical Cage System should be used with the provided bone screws and requires no additional supplementary fixation systems.

TECHNOLOGICAL CHARACTERISTICS

The Cavetto®-SA 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 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**
K173077	Cavetto-SA Cervical Cage System	NeuroStructures	Primary
K172064	Ti-Diagon Oblique TLIF	Camber Spine Technologies	Reference
K172320	Cavetto® Cervical Cage System	NeuroStructures, Inc.	Reference
K142041	PorOsteon Phusion Metal Cervical Cage	PorOsteon, Inc.	Reference
K153097	Belvedere™ Lateral Plating System	Neurostructures	Reference

PERFORMANCE DATA

A comparison of the previously cleared device material and the subject device material was completed *in lieu* of mechanical testing.

CONCLUSION

The overall technology and material characteristics lead to the conclusion that the Cavetto®-SA Cervical Cage System is substantially equivalent to the predicate device.