DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Neurostructures, Incorporation
% Mr. Kenneth Maxwell II
Regulatory and Quality Specialist
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, Colorado 80918

July 15, 2016

Re: K153097
Trade/Device Name: Belvedere™ Lateral Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 9, 2016
Received: June 10, 2016

Dear Mr. Maxwell:

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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153097

Device Name
Belvedere™ Lateral Plating System

Indications for Use *(Describe)*
The Neurostructures Belvedere™ Lateral Plating System is indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (T1-L5) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of disco genic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

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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510(K) SUMMARY

Submitter's Name:	Neurostructures, Inc.
Submitter's Address:	16 Technology Dr. Suite 165 Irvine, CA 92618
Submitter's Telephone:	800.352.6103
Contact Person:	Kenneth C. Maxwell II Empirical Consulting LLC 719.291.6874
Date Summary was Prepared:	11 July 2016
Trade or Proprietary Name:	Belvedere™ Lateral Plating System
Common or Usual Name:	Appliance, Fixation, Spinal Intervertebral Body
Classification:	Class II per 21 CFR §888.3060
Product Code:	KWQ
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Belvedere™ Lateral Plating System provides an assortment of thoracic and thoracolumbar plates and screws. The plates and screws provided are manufactured from titanium alloy 6AL-4V-ELI per ASTM F-136. Multiple variations of the screws are provided in lengths of 20-70mm and diameters of 5.0-6.5mm. The plates are provided in lengths of 36-132mm.

INDICATIONS FOR USE

The NeuroStructures Belvedere™ Lateral Plating System is indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (Tl - L5) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of disco genic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

The indications for use for the Belvedere™ Lateral Plating System are similar to that of predicate devices listed in Table 5-1 Predicate Devices.

TECHNOLOGICAL CHARACTERISTICS

The Belvedere™ Lateral Plating System and the 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:

- Indications for Use
- Materials of manufacture
- Principles of operation

Table 5-1 Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Type
K020244	Thoracolumbar Spine Locking Plate (TSLP) System	Synthes	Primary
K133194	Black/Red Diamond Rattlesnake Lumbar Plating System	Eminent Spine	Additional
K143230	Palladian™ Lumbar Pedicle Screw System	Neurostructures, Inc.	Reference

PERFORMANCE DATA

The Belvedere™ Lateral Plating System has been tested in the following test modes:

- Static axial compression bending per ASTM F1717-14
- Static torsion per ASTM F1717-14
- Static tension per ASTM F1717-14
- Dynamic axial compression bending per ASTM F1717-14

The results of this non-clinical testing show that the strength of the Belvedere™ Lateral Plating 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 Belvedere™ Lateral Plating System is substantially equivalent to the predicate device.