



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

NeuroPro Spinal Jaxx, Incorporated
c/o Rich Jansen, Pharm.D.
Consultant
Silver Pine Consulting, LLC
11821 Bramble Cove Drive
Fort Myers, Florida 33905

June 29, 2016

Re: K152501

Trade/Device Name: Spinal Jaxx Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 3, 2016
Received: June 6, 2016

Dear Dr. Jansen:

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

Indications for Use

510(k) Number (if known)

K152501

Device Name

Spinal Jaxx Interbody Fusion Device

Indications for Use (Describe)

The Spinal Jaxx interbody fusion device is indicated for spinal fusion for patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2 – S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The indicated patient population is skeletally mature patients who have had six (6) months of non-operative treatment. The Spinal Jaxx interbody fusion device must be used with autogenous bone graft material and 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
Spinal Jaxx Interbody Fusion System

Date Prepared: June 24, 2016
Company: NeuroPro Spinal Jaxx, Inc.
4707 Greenleaf Ct., Ste. C
Modesto, CA 95356
Contact: John Green, COO
Jgreen@neuroprotech.com
571-334-7424
Regulatory Contact: Rich Jansen, Pharm. D.
Silver Pine Consulting
Device Name: Spinal Jaxx Interbody Fusion Device
Classification: Per 21 CFR 888.3080
Intervertebral Body Fusion Device
Product Code: MAX
Regulatory Class II
Panel Code 87
Predicate Devices: The primary predicate is the CALIBER™ Spacer (K102293). Additional predicate devices include the Rise Spacer (K113447), Brantigan Cage (AKA: LT Cage & Jaguar Cage) (P960025), Ray Threaded Fusion Cage (P950019), Patriot Spacer (K072970) and the Nanovis Foricore device (K140280)

Purpose:

The purpose of this submission is clearance of the Spinal Jaxx Interbody Fusion Device as a new medical device that is substantially equivalent to the predicate devices.

Device Description:

The Spinal Jaxx Interbody Fusion device is a lumbar intervertebral spacer intended to provide structural stability in a skeletally mature individual based on the surgical intervention by the surgeon. The physician can insert it into the diseased disc space and adjust the height of the device as desired to create near normal disc height. The implants are made from PEEK Optima LT1, a medical grade titanium alloy, CP titanium and Nitinol. Implants are available in various sizes to accommodate patient anatomy. Instruments are made from stainless steel, aluminum, Nitinol, and silicone rubber.

Indications for Use:

The Spinal Jaxx interbody fusion device is indicated for spinal fusion for patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2 – S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The indicated patient population is skeletally mature patients who have had six (6) months of non-operative treatment. The Spinal Jaxx interbody fusion device must be used with autogenous bone graft material and with supplemental fixation.

Performance Data:

To demonstrate substantial equivalence to the predicate devices, mechanical testing was conducted in accordance with “Class II Special Controls Guidance Document: Intervertebral Fusion Device, June 12, 2007” including the ASTM standards:

- Static Compression and Static Compression Shear testing per ASTM F2077
- Dynamic Axial Compression and Dynamic Compression Shear testing per ASTM F2077
- Subsidence Testing per ASTM F2267-04
- Static Expulsion/Industry Standard per ASTM Draft Standard F-04.25.02.02
- Wear Debris analysis per ASTM F1877-05
- Cyclic Potentiodynamic Polarization Testing per ASTM F2129-15

Technological Characteristics:

NeuroPro has compared the Spinal Jaxx Interbody Fusion System to the predicate devices in regards to indications for use, materials, function, sizes and mechanical test results. These comparisons demonstrate substantial equivalence to the predicate devices.

Conclusions:

The Spinal Jaxx Interbody Fusion System is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.