



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

Nexus Spine, LLC  
Jared Crocker  
President  
2825 East Cottonwood Parkway, Suite 330  
Salt Lake City, Utah 84121

June 28, 2016

Re: K160820  
Trade/Device Name: PressON Pro Spinal Fixation System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class III  
Product Code: NKB, MNH, MNI  
Dated: June 3, 2016  
Received: June 7, 2016

Dear Mr. Crocker:

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)

K160820

Device Name

PressON Pro Spinal Fixation System

Indications for Use (Describe)

The PressON Pro Spinal Fixation System is a posterior, non-cervical pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, dislocation, scoliosis, kyphosis, lordosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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)

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

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## 510(k) Summary

<b>Submitter:</b>	Nexus Spine LLC
<b>Contact Person:</b>	Mr. Jared Crocker, President 2825 East Cottonwood Parkway Suite 330 Salt Lake City, UT 84121 Telephone: (801) 702-8592 Fax: (801) 702-8585
<b>Date Prepared:</b>	March 15, 2016
<b>Trade Name:</b>	PressON Pro Spinal Fixation System
<b>Classification, Name and Number:</b>	Class III Pedicle Screw Spinal System 21 CFR 888.3070
<b>Product Code:</b>	MNI, MNH and NKB
<b>Predicate Device(s):</b>	The subject device is substantially equivalent to the following devices:  <i>PressON Pedicle Screw System (Primary Predicate)</i> Marketed and distributed by Nexus Spine, LLC 510(K) Number: K133287  <i>Expedium MOSS Miami Spinal System</i> Marketed and distributed by Johnson & Johnson 510(K) Number K103490  <i>Alpine Pedicle Screw System</i> Marketed and distributed by Sanacor LLC 510(K) Number K090477
<b>Device Description:</b>	The PressON Pro Spinal Fixation System is composed of pedicle screws and rods. These components can be assembled and implanted using associated instruments via a posterior approach into the pedicles of the noncervical vertebral bodies. Components are made from Ti-6Al-4V ELI (ASTM F-136).
<b>Intended Use:</b>	The PressON Pro Spinal Fixation System is a posterior, non-cervical pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed



by history and radiographic studies), spondylolisthesis, fracture, dislocation, scoliosis, kyphosis, lordosis, spinal tumor, and failed previous fusion (pseudarthrosis).

**Statement of  
Technological  
Comparison:**

The PressON Pro Spinal Fixation System is substantially equivalent to the above listed predicate devices in terms of materials, design, indications for use and operational principles.

**Performance Data:**

Verification activities were performed, including mechanical testing as follows: axial load, A/P load, axial torsion, and flexion/extension load per ASTM F1798-13; and static torsion, static compression bending, and dynamic compression bending per ASTM F1717-14.

**Conclusion:**

Documentation provided demonstrates the PressON Pro Spinal Fixation System is substantially equivalent to predicate devices.