



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

Spinal Balance, Inc.  
% Karen E. Warden, Ph.D.  
President  
BackRoads Consulting, Inc.  
P.O. Box 566  
Chesterland, Ohio 44026-0566

October 27, 2016

Re: K162750  
Trade/Device Name: Libra Pedicle Screw System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class III  
Product Code: NKB, MNI, MNH  
Dated: September 28, 2016  
Received: September 30, 2016

Dear Dr. Warden:

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,

**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)

K162750

Device Name

Libra Pedicle Screw System

Indications for Use (Describe)

The Libra Pedicle Screw System is intended for immobilization and stabilization of the posterior thoracic, lumbar and sacral/iliac spine (T1-S1/Ilium) in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

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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## **Section 8 – 510(k) Summary**

|                                       |   |
|---------------------------------------|---|
| <b>Date:</b>                          | 28 September 2016   |
| <b>Sponsor:</b>                       | Spinal Balance, Inc.<br>Nitschke Technology Commercialization Complex (NTCC)<br>1510 N. Westwood Ave<br>Toledo OH 43606<br>440.530.5940   |
| <b>Sponsor Contact:</b>               | Anand Agarwal, MD, President and CEO  |
| <b>510(k) Contact:</b>                | Karen E. Warden, PhD<br>BackRoads Consulting, Inc.<br>PO Box 566<br>Chesterland, OH 44026<br>Office: 440.729.8457   |
| <b>Proposed Trade Name:</b>           | Libra Pedicle Screw System  |
| <b>Common Name:</b>                   | Posterior pedicle screw system  |
| <b>Device Classification:</b>         | Class III   |
| <b>Classification Name:</b>           | Pedicle screw spinal system   |
| <b>Regulation:</b>                    | 888.3070  |
| <b>Device Product Code:</b>           | NKB, MNI, MNH   |
| <b>Submission Purpose:</b>            | To add a cobalt chrome rod series to the Libra Pedicle Screw System implant offering.   |
| <b>Device Description:</b>            | The Libra Pedicle Screw System consists of longitudinal members (rods), anchors (screws) and fasteners in a variety of sizes to accommodate differing anatomic requirements.  |
| <b>Indications for Use:</b>           | The Libra Pedicle Screw System is intended for immobilization and stabilization of the posterior thoracic, lumbar and sacral/ilium spine (T1-S1/Ilium) in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion. |
| <b>Materials:</b>                     | Libra components are manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F136). Rods are additionally manufactured from cobalt chrome (ASTM F1537).  |
| <b>Predicate Device:</b>              | Primary: Libra Pedicle Screw System (Spinal Balance, Inc. – K151770)  |
| <b>Performance Data:</b>              | Theoretical analysis of the proposed device modification was performed. The results demonstrate the cobalt chrome rod does not create a new worst case.   |
| <b>Technological Characteristics:</b> | The Libra Pedicle Screw System possesses the same technological characteristics as the predicate device. These include: <ul style="list-style-type: none"> <li>• intended use (as described above)</li> <li>• basic design (rod and screw configuration),</li> <li>• material (medical grade),</li> <li>• sizes (dimensions are comparable to those offered by the predicate systems) and</li> </ul> <p>The fundamental scientific technology of the Libra Pedicle Screw System is the same as previously cleared device.</p>   |

**Conclusion:**

The Libra Pedicle Screw System possesses the same intended use and technological characteristics as the predicate devices. Therefore Libra Pedicle Screw System is substantially equivalent for its intended use.