



Food and Drug Administration
10903 New Hampshire Avenue
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Spinal Balance, Incorporated
% Karen E. Warden, Ph.D.
BackRoads Consulting, Incorporated
P.O. Box 566
Chesterland, OH 44026

November 20, 2015

Re: K151770
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: October 27, 2015
Received: October 28, 2015

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" (21 CFR 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)
K151770

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)

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

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510(k) Summary

Date: 29 June 2015

Sponsor: Spinal Balance Inc.
Nitschke Technology Commercialization Complex (NTCC)
1510 N. Westwood Ave
Toledo OH 43606
440.530.5940

Sponsor Contact: Anand Agarwal, MD, President and CEO

510(k) Contact: Karen E. Warden, PhD
BackRoads Consulting Inc.
PO Box 566
Chesterland, OH 44026
Office: 440.729.8457

Proposed Trade Name: Libra Pedicle Screw System

Common Name: Posterior pedicle screw system

Device Classification: Class III

Classification Name: Pedicle screw spinal system

Regulation: 888.3070

Device Product Code: MNI, MNH, NKB

Device Description: The Libra Pedicle Screw System consists of longitudinal members (rods), anchors (screws) and fasteners in a variety of sizes to accommodate differing anatomic requirements.

Indications for Use: 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.

Materials: Libra components are manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F136)

Predicate Devices: Primary: Tiger® Spine System (Corelink, LLC – K133369)
Additional: CD Horizon® Spinal System (Medtronic Sofamor Danek – K143569), Radius® Spinal System (Stryker Spine – K101144) and Foundation Spinal System (Skeletal Design Partnership – K120074)

Reference Devices: Moss Miami™ Spinal System (DePuy AcroMed, Inc. – K022623), Optima™ Spinal System (U&I Corporation – K051971)

Performance Data: Mechanical testing of worst case Libra Pedicle Screw System constructs included static and dynamic compression bending and static torsion according to ASTM F1717.
The mechanical test results demonstrate that Libra Pedicle Screw System performance is substantially equivalent to the predicate devices.

**Technological
Characteristics:**

The Libra Pedicle Screw System possesses the same technological characteristics as one or more of the predicate devices. These include: intended use (as described above)
basic design (rod and screw configuration),
material (titanium alloy),
sizes (dimensions are comparable to those offered by the predicate systems) and
The fundamental scientific technology of the Libra Pedicle Screw System is the same as previously cleared devices.

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.