



Food and Drug Administration
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Spine Wave, Incorporated
Ms. Kelly Barbieri
Senior Director, Quality
3 Enterprise Drive, Suite 210
Shelton, Connecticut 06484

February 26, 2016

Re: K160003
Trade/Device Name: Sniper[®] Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: December 31, 2015
Received: January 4, 2016

Dear Ms. Barbieri:

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)

K160003

Device Name

Sniper® Spine System

Indications for Use (Describe)

The Sniper® Spine System is a non-cervical spinal fixation system intended for posterior pedicle screw fixation (T1-S2/ilium) in skeletally mature patients. The Sniper® Spine System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The Sniper® Spine System is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3-S2/ilium), and for whom the device is intended to be removed after solid fusion is attained.

The Sniper® Spine System percutaneous instruments are intended to be used with the Sniper® System Implants. The instruments, when used with the percutaneous cannulated screws and percutaneous rods, are intended to provide the surgeon with a percutaneous approach for posterior spinal surgery for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The instruments are also intended to provide a percutaneous approach for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3-S2/ilium), and for whom the device is intended to be removed after solid fusion is attained.

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 Sniper[®] Spine System

1. Submitter Information

Submitter: Spine Wave, Inc.
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Shelton, CT 06484
Telephone: 203-712-1804
Telefax: 203-944-9493

Contact: Kelly Barbieri
Date Prepared: December 31, 2015

2. Device Information

Trade Name: Sniper[®] Spine System
Common Name: Pedicle Screw Spinal System
Classification Name: Pedicle Screw Spinal System
Classification/Code: Class II per 21 CFR 888.3070 / MNH, MNI

3. Purpose of Submission

The purpose of this submission is to gain clearance for additional components for the Sniper[®] Spine System, including additional screw sizes, cobalt chrome alloy rods and offset connectors. The indications for use are also being modified as a result of these line additions.

4. Predicate Device Information

The Sniper[®] Spine System described in this submission is substantially equivalent to the following predicates:

| | Predicate Device | Manufacturer | 510(k) No. |
|----------------------|----------------------------------|---------------------|-------------------|
| Primary Predicate | Sniper [®] Spine System | Spine Wave, Inc. | K152174 |
| Additional Predicate | CapSure [®] PS System | Spine Wave, Inc. | K132154 |

5. Device Description

The Sniper[®] Spine System consists of a selection of non-sterile, single use, titanium alloy screw and connector components, and titanium alloy and cobalt chrome alloy rod components that are assembled to create a rigid spinal construct. The components of the Sniper[®] Spine System are attached to the non-cervical spine in order to stabilize the spine during fusion of the vertebral bodies, and are intended to be removed after spinal fusion is achieved.

6. Indications for Use

The Sniper[®] Spine System is a non-cervical spinal fixation system intended for posterior pedicle screw fixation (T1-S2/ilium) in skeletally mature patients. The Sniper[®] Spine System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The Sniper[®] Spine System is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3-S2/ilium), and for whom the device is intended to be removed after solid fusion is attained.

The Sniper[®] Spine System percutaneous instruments are intended to be used with the Sniper[®] System Implants. The instruments, when used with the percutaneous cannulated screws and percutaneous rods, are intended to provide the surgeon with a percutaneous approach for posterior spinal surgery for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The instruments are also intended to provide a percutaneous approach for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3-S2/ilium), and for whom the device is intended to be removed after solid fusion is attained.

7. Comparison of Technological Characteristics

The substantial equivalence of the subject Sniper[®] Spine System to the predicates is shown by similarity in intended use, indications for use, materials and performance.

8. Performance Data

Performance evaluations were previously conducted on constructs representing the worst case components (including static torsion, static axial compression and dynamic axial compression bending in accordance with ASTM F1717). Engineering rationales determined that the proposed implants were substantially the same as the predicate devices.

9. Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicates, the subject Sniper[®] Spine System has been shown to be substantially equivalent to the predicate devices identified in this submission, and does not present any new issues of safety or effectiveness.