DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 31, 2015

Spine Wave, Incorporated
Mr. Ronald K. Smith
Executive Vice President
Quality, Regulatory & Clinical Affairs
Three Enterprise Drive, Suite 210
Shelton, Connecticut 06484

Re: K151813
Trade/Device Name: Sniper® Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: July 1, 2015
Received: July 2, 2015

Dear Mr. Smith:

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 Part 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151813

Device Name

Sniper® Spine System

Indications for Use *(Describe)*

When used as a pedicle screw fixation system of the noncervical spine 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-S1), 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® Spine System implants. The percutaneous 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). As well as, 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-S1), 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.

510(k) Summary
Sniper® Spine System

1. Submitter Information

Submitter: Spine Wave, Inc.
Address: Three Enterprise Drive
Suite 210
Shelton, CT 06484
Telephone: 203-712-1846
Telefax: 203-944-9493

Contact: Ronald K. Smith

Date Prepared: July 1, 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; MNI, MNH

3. Purpose of Submission

The purpose of this submission is to gain clearance for the additional length rods to the cleared Sniper® Spine System.

4. Predicate Device Information

The Sniper® Spine System described in this submission is substantially equivalent to the following primary predicate:

Predicate Device	Manufacturer	510(k) No.
MIS Pedicle Screw System	Spine Wave, Inc.	K100605

5. Device Description

The Sniper® Spine System consists of a selection of non-sterile, single use titanium alloy rod and screw components that are assembled to create a rigid spinal construct. The rod and screw 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

When used as a pedicle screw fixation system of the noncervical spine 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-S1), 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® Spine System implants. The percutaneous 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). As well as, 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-S1), 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 is shown by similarity in intended use, indications for use, materials and performance to the cited predicate device.

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 a predicate, the subject Sniper® Spine System has been shown to be substantially equivalent to the predicate device identified in this submission.