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

Spine Wave, Inc.
Amy Noccioli
Regulatory Affairs Specialist
3 Enterprise Drive, Suite 210
Shelton, Connecticut 06484

August 16, 2017

Re: K172175
Trade/Device Name: CapSure® PS System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbar Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: July 18, 2017
Received: July 19, 2017

Dear Amy Noccioli:

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,

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)*

K172175

Device Name
CapSure® PS System

Indications for Use *(Describe)*

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

The CapSure® PS 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.

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
CapSure® PS System

1. Submitter Information

Submitter: Spine Wave, Inc.
Address: Three Enterprise Drive
Suite 210
Shelton, CT 06484
Telephone: 203-712-1842
Telefax: 203-944-9493

Contact: Amy Noccioli

Date Prepared: August 11, 2017

2. Device Information

Trade Name: CapSure® PS System
Common Name: Pedicle Screw Spinal System
Classification: Class II per 21 CFR 888.3070
Classification Name: Thoracolumbosacral Pedicle Screw System
Product Code: NKB

3. Purpose of Submission

The purpose of this submission is to gain clearance for the 4.75 mm diameter cobalt-chrome straight rod and dual-diameter titanium rod additions to the previously cleared CapSure® PS System.

4. Predicate Device Information

The CapSure® PS System described in this submission is substantially equivalent to the following predicate:

Predicate Device	Manufacturer	510(k) No.
CapSure® PS System	Spine Wave, Inc.	K132154

5. Device Description

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

6. Indications for Use

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

The CapSure® PS 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.

7. Comparison of Technological Characteristics

The subject CapSure® PS System has technological characteristics similar to the predicate device, including intended use and indications for use, performance, design, and material composition. The only difference between the subject device and the predicate device is the addition of 4.75 mm diameter cobalt-chrome straight rods and dual-diameter titanium rods.

8. Performance Data

Spine Wave, Inc. performed dynamic axial compression bend testing on the worst-case samples of the modified implants in accordance with ASTM F1717**.** The results of this testing show that the modified implants do not represent a new worst case for the system and are therefore substantially equivalent to the predicate device.

9. Conclusion

The indications for use, technological characteristics, and comparison to the predicate show that the subject CapSure® PS System is substantially equivalent to the predicate device identified in this submission, and does not present any new issues of safety or effectiveness.