DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Senecka Spine
% Rich Jansen, Pharm.D.
Silver Pine Consulting, LLC
11821 Bramble Cove Drive
Fort Myers, Florida 33905

January 28, 2016

Re: K153525
Trade/Device Name: Seneka II Polyscrew Pedicle Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP, KWQ
Dated: December 22, 2015
Received: December 24, 2015

Dear Dr. Jansen:

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)*
K153525

Device Name
Seneka II Polyscrew Pedicle Fixation System

Indications for Use *(Describe)*
The Seneka II Polyscrew Pedicle Fixation System is intended for posterior non-cervical fixation as an adjunct to fusion in skeletally mature patients for the following indications: degenerative disc disease (DDD) (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, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. Except for hooks, when used as an anterolateral thoracic/lumbar system the Seneka II Polyscrew Pedicle Fixation System may also be used for the same indications as an adjunct to 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date Prepared: January 20, 2016

Contact: Khalid Sethi
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Regulatory Contact: Rich Jansen, Pharm. D.
Silver Pine Consulting, LLC
richj@s-pineconsulting.com

Trade Names: Seneka II Polyscrew Pedicle Fixation System
Product Class: Class III
Classification: 21 CFR §888.3070 Pedicle Screw Spinal System,
§888.3060 Spinal Intervertebral Body Fixation Orthosis, and
§888.3050 Spinal Interlaminal Fixation Orthosis
Common Name: Pedicle Screw System
Product Codes: NKB, MNI, MNH, KWQ, KWP
Panel Code: 87

Indications for Use:
The Seneka II Polyscrew Pedicle Fixation System is intended for posterior non-cervical fixation as an adjunct to fusion in skeletally mature patients for the following indications: degenerative disc disease (DDD) (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, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. Except for hooks, when used as an anterolateral thoracic/lumbar system the Seneka II Polyscrew Pedicle Fixation System may also be used for the same indications as an adjunct to fusion.

Device Descriptions:
The Seneka II Polyscrew Pedicle Fixation System is comprised of: straight and pre-curved rods, pedicle screw assemblies with both cannulated and non-cannulated screws, reduction screws, domino connectors, offset connectors, hooks and a set screw. Various forms and sizes of these implants are available so that adaptations can be utilized to take into account the unique pathology of individual patients. The Seneka II system can be implanted via the open surgical approach.
Components are made of Ti6Al4V ELI, a titanium based alloy, which complies with ASTM F136, cobalt chrome per ASTM F1537 or CP Titanium per ASTM E2371-13.

Predicate Device(s):
The Seneka II Polyscrew Pedicle Fixation System is substantially equivalent to the primary predicate device which is the Seneka I System from Senecka Spine (K151849). Additional predicate devices include Scien'tx USA Inc. ISOBAR Spinal System (K013444) and the K2M Inc. Everest Spinal System (K151216).

Performance Standards:
The pre-clinical testing performed includes static and dynamic compression bending, and static torsion per ASTM F1717-14.

Technological Characteristics:
Senecka Spine has compared the Seneka II Polyscrew Pedicle Fixation System to the predicate devices in regards to indications for use, materials, function, sizes and mechanical test results. These comparisons demonstrate substantial equivalence to the predicate devices.

Conclusion:
Senecka Spine concludes that the Seneka II Polyscrew Pedicle Fixation System is substantially equivalent to the predicate devices and raises no new questions of safety or effectiveness.