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

February 7, 2017

Spine Wave, Inc.
Ms. Sanja Jahr
Regulatory Affairs Specialist
Three Enterprise Drive, Suite 210
Shelton, Connecticut 06484

Re: K162639
Trade/Device Name: Proficient™ Posterior Cervical Spine System
Regulatory Class: Unclassified
Product Code: NKG
Dated: January 5, 2017
Received: January 6, 2017

Dear Ms. Jahr:

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)*
K162639

Device Name
Proficient™ Posterior Cervical Spine System

Indications for Use *(Describe)*
The Proficient™ Posterior Cervical Spine System is intended to immobilize and stabilize the spine as an adjunct to fusion for cervical (C2-C7) and thoracic (T1-T3) spinal segments that have been affected by the following acute or chronic instabilities: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative diseases, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies and degenerative disease of the facets with instability. The Proficient™ Posterior Cervical Spine System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the cervical spine whose life expectancy is insufficient to permit achievement of fusion. In order to achieve additional levels of fixation, the Proficient™ Posterior Cervical Spine System may be connected to the CapSure® Spine System or the Sniper® Spine System using the Proficient™ transition rods.

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
Proficient™ Posterior Cervical Spine System

1. Submitter Information

Submitter:	Spine Wave, Inc.
Address:	Three Enterprise Drive Suite 210 Shelton, CT 06484
Telephone:	203-712-1870
Telefax:	203-944-9493
Contact:	Sanja Jahr
Date Prepared:	January 5, 2016

2. Device Information

Trade Name:	Proficient™ Posterior Cervical Spine System
Common Name:	Posterior Cervico-Thoracic Fixation system
Classification:	Unclassified, Pre-Amendment
Classification Name:	Orthosis, Cervical Pedicle Screw Spinal Fixation
Product Code:	NKG

3. Purpose of Submission

The purpose of this submission is to gain clearance for a new posterior cervico-thoracic fixation system.

4. Predicate Device Information

The Proficient™ Posterior Cervical Spine System described in this submission is substantially equivalent to the following predicates:

Primary Predicate Device	**Manufacturer**	**510(k) No.**
Synapse™ OCT System	DePuy Synthes, Inc.	K142838

Reference Predicate Devices	**Manufacturer**	**510(k) No.**
neon^{3} ™	Ulrich Medical	K150650
Zero-P™ VA	Synthes Spine, Inc.	K112068
Mountaineer® OCT Spinal System	Depuy Synthes Inc.	K151885
Virage® OCT Spinal Fixation System	Zimmer Spine, Inc	K153631

5. Device Description

The Proficient™ Posterior Cervical Spine System consists of a selection of non-sterile, single use polyaxial screws, set screws, rods, and cross-connector components manufactured from titanium (ASTM F136 and ASTM F67) and cobalt chrome alloys (ASTM F1537 and ASTM F1058). The surgeon attaches the rod, screw, and cross connectors to the cervicothoracic region of the spine in order to stabilize the spine during fusion of vertebral bodies.

6. Indications for Use

The Proficient™ Posterior Cervical Spine System is intended to immobilize and stabilize the spine as an adjunct to fusion for cervical (C2-C7) and thoracic (T1-T3) spinal segments that have been affected by the following acute or chronic instabilities: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative diseases, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies and degenerative disease of the facets with instability. The Proficient™ Posterior Cervical Spine System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the cervical spine whose life expectancy is insufficient to permit achievement of fusion. In order to achieve additional levels of fixation, the Proficient™ Posterior Cervical Spine System may be connected to the CapSure® Spine System or the Sniper® Spine System using the Proficient™ transition rods.

7. Comparison of Technological Characteristics

The substantial equivalence of the Proficient™ Posterior Cervical Spine System to the predicates is demonstrated by similarity in indications for use, materials and performance.

8. Performance Data

Spine Wave performed the following testing to demonstrate the Proficient™ Posterior Cervical Spine System is substantially equivalent to its predicate:

- Static and dynamic compression bending (per ASTM F1717)
- Static and dynamic torsion (per ASTM F1717)
- Axial grip (per ASTM 1798)

9. Conclusion

Based on the indications for use, technological characteristics, performance testing and comparison to the predicates, the Proficient™ Posterior Cervical 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.