



December 15, 2017

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

Re: K172594

Trade/Device Name: Proficient® Posterior Cervical Spine System

Regulatory Class: Unclassified

Product Code: NKG

Dated: November 21, 2017

Received: November 22, 2017

Dear Ms. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
Ronald P. Jean -S for

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)

K172594

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 (C1-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: 203-712-1842  
Telefax: 203-944-9493  
Contact: Amy Noccioli  
Date Prepared: November 21, 2017

### 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  
*Classification Code:* NKG

### 3. Purpose of Submission

The purpose of this submission is to gain clearance for the addition of new variations of connectors and polyaxial screws to the previously cleared Proficient® Posterior Cervical Spine System and to expand the indications for use to C1.

### 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.
Proficient® Posterior Cervical Spine System	Spine Wave, Inc.	K162639

  

Additional Predicate Devices	Manufacturer	510(k) No.
Lineum OCT Spine System	Biomet	K151224
Synapse OCT System	Synthes	K142838

## **5. Device Description**

The subject Proficient<sup>®</sup> Posterior Cervical Spine System consists of a selection of non-sterile, single-use polyaxial screws, locking screws, rods, and connectors manufactured from titanium per ASTM F136 and ASTM F67 and cobalt-chrome alloys per ASTM F1537 and ASTM F1058. The rods, screws, and connectors are attached to the cervicothoracic spine of skeletally mature patients to stabilize the spine during fusion of vertebral bodies.

## **6. Indications for Use**

The Proficient<sup>®</sup> Posterior Cervical Spine System is intended to immobilize and stabilize the spine as an adjunct to fusion for cervical (C1-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<sup>®</sup> 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<sup>®</sup> Posterior Cervical Spine System may be connected to the CapSure<sup>®</sup> Spine System or the Sniper<sup>®</sup> Spine System using the Proficient<sup>®</sup> transition rods.

## **7. Comparison of Technological Characteristics**

The subject Proficient<sup>®</sup> Posterior Cervical Spine System has technological characteristics similar to those of the predicates, including intended use and indications for use, performance, design, and material composition.

## **8. Performance Data**

Spine Wave, Inc. performed dynamic axial compression bend testing, dynamic torsional testing, and static and axial grip testing to demonstrate substantial equivalence.

## **9. Conclusion**

The indications for use, technological characteristics, and performance data show that the subject Proficient<sup>®</sup> Posterior Cervical Spine System is substantially equivalent to the predicates identified in this submission, and does not present any new issues of safety or effectiveness.