July 30, 2018

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

Re: K181440
Trade/Device Name: Proficient® Posterior Cervical Spine System
Regulatory Class: Unclassified
Product Code: NKG
Dated: May 30, 2018
Received: June 1, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181440

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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SPINE WAVE

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:	May 30, 2018

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 components to the previously cleared Proficient® Posterior Cervical Spine System and for a modification to instrumentation supplied for use with the system.

4. Predicate Device Information

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

Primary Predicate Device	Manufacturer	510(k) No.
Proficient® Posterior Cervical Spine System	Spine Wave, Inc.	K172594

5. Device Description

The modified Proficient® 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® 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.

7. Comparison of Technological Characteristics

The subject Proficient® Posterior Cervical Spine System has technological characteristics similar to the predicate device, 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 axial grip testing on the subject device to demonstrate that the subject device is substantially equivalent to the predicate device in performance testing.

9. Conclusion

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