March 16, 2022

Precision Spine, Inc.
℅ Lisa Ferrara, PhD
Technical Director
Element Materials Technology
3701 Port Union Road
Farfield, Ohio 45014

Re: K220324
Trade/Device Name: AccuFit Lateral 2-Hole Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 3, 2022
Received: February 3, 2022

Dear Lisa Ferrara:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O’Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220324

Device Name
AccuFit® Lateral Plate System

Indications for Use *(Describe)*
The AccuFit® Lateral Plate System is indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery. The device is intended as a temporary fixation device until fusion is achieved.

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

Device Trade Name: AccuFit® Lateral 2-Hole Plate

Manufacturer:
Precision Spine, Inc.
2050 Executive Dr.
Pearl, Mississippi 39208
United States

Contact:
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3701 Port Union Road
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Date Prepared: February 3, 2022

Classification: 21 CFR §888.3060, Spinal intervertebral body fixation orthosis

Class: II

Product Codes: KWQ

Indications for Use:
The AccuFit® Lateral Plate System is indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine

instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery. The device is intended as a temporary fixation device until fusion is achieved.

Device Description:
The AccuFit® Lateral 2-Hole Plate consists of non-sterile, single use, titanium alloy (Ti-6AI-4V ELI per ASTM F136) rigid plates and screws of varying sizes. The plate attaches by means of screws to the lateral portion of the vertebral body. The AccuFit® Lateral 2-Hole Plate (Subject Device) will be implanted using the instruments cleared with the AccuFit® Lateral Plate System (K162211), however a new inserter and tray will be introduced to the system that is to be used with the AccuFit® Lateral 2-Hole Plate (Subject Device). The AccuFit® Lateral 2-Hole Plate is to be provided non-sterile. They require sterilization prior to use.

Primary Predicate Devices:
The AccuFit® Lateral 2-Hole Plate is substantially equivalent in device indications, design and performance to the following primary predicate device.

- AccuFit® Lateral Plate System, Precision Spine, K162211

Additional Predicate Devices:
The following additional predicate device is presented to further demonstrate substantial equivalence since this device contributes incremental benefit to the substantial equivalence profile with the device indications, design, mechanical performance, and clinical performance:

- LITe® Plate System, Stryker, K150449

Performance Testing Summary:

The testing of the AccuFit® Lateral 2-Hole Plate includes:

- Static Compression Bending per ASTM F1717
- Static Torsion per ASTM F1717
- Dynamic Compression Bending per ASTM F1717

Comparison of Technological Characteristics:

The AccuFit® Lateral 2-Hole Plate has the same indications for use, materials, and similar design features as compared to the predicate devices. The bench testing demonstrates that the performance characteristics of the AccuFit® Lateral 2-Hole Plate is equivalent to those of other legally marketed spinal intervertebral body fixation orthoses, and therefore supports a determination of Substantial Equivalence for the proposed indications for use. Any differences between the subject and predicate devices would not render the device NSE, affect the safety or effectiveness, or raise different questions of safety and effectiveness.

Substantial Equivalence

The subject device was demonstrated to be substantially equivalent to the predicate cited in the passage above with respect to indications, design, function and performance.

Conclusion:

The AccuFit® Lateral 2-Hole Plate is substantially equivalent to the cited predicate device with respect to indications for use, design, function, and performance.