October 19, 2022

Stryker Corporation
Katie McNeil
Senior Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K221728
Trade/Device Name: Aviator® Anterior Cervical Plating (ACP) System, LITe® Plate System, DynaTran™ Anterior Cervical Plating (ACP) System, Reflex™ Hybrid ACP System, UniVise™ Spinous Process Fixation Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: September 22, 2022
Received: September 22, 2022

Dear Katie McNeil:

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,

for

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)*
K221728

Device Name
Aviator® Anterior Cervical Plating (ACP) System

Indications for Use *(Describe)*
The Aviator® Anterior Cervical Plating System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

- Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Failed previous fusion
- Decompression of the spinal cord following total or partial cervical vertebrectomy
- Spondylolisthesis
- Spinal stenosis

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)

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

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510(k) Number *(if known)*
K221728

Device Name
LITe® Plate System

Indications for Use *(Describe)*
The LITe® Plate System Universal, Sacral, 2 Screw and 4 Screw Plates are indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of the thoracic and thoracolumbar (T1-L5) spine or via an anterior approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine. The system is intended to provide additional support during fusion in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);
- Pseudoarthrosis;
- Spondylolysis;
- Spondylolisthesis;
- Spinal stenosis;
- Tumors;
- Trauma (i.e. Fractures or Dislocation)
- Deformities (i.e. Scoliosis, Kyphosis or Lordosis)
- Failed Previous Fusion

The LITe® Plate System Buttress Plate is intended to stabilize the allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

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)

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510(k) Number *(if known)*
K221728

Device Name
DynaTran™ Anterior Cervical Plating (ACP) System

Indications for Use *(Describe)*
The DynaTran™ Anterior Cervical Plating System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

- Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Failed previous fusion
- Decompression of the spinal cord following total or partial cervical vertebrectomy
- Spondylolisthesis
- Spinal stenosis

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221728

Device Name
Reflex™ Hybrid ACP System

Indications for Use *(Describe)*
The Reflex™ Hybrid ACP System is intended for anterior intervertebral screw fixation of the cervical spine from C2 – T1. These systems are indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

- Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Decompression of the spinal cord following total or partial cervical vertebrectomy
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis or scoliosis)
- Pseudoarthrosis
- Failed previous fusions
- Spondylolisthesis
- Spinal stenosis

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)

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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)*
K221728

Device Name
UniVise™ Spinous Process Fixation Plate

Indications for Use *(Describe)*
The UniVise™ Spinous Process Fixation Plate is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (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); and/or tumor. The UniVise™ Spinous Process Fixation Plate is intended for use with bone graft and not intended for stand-alone use.

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)

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510(k) Summary: Stryker Spine Plate Systems	
Submitter:	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person :	Name: Katie McNeil Phone: 201-749-8518 Email: katie.mcneil@stryker.com
Date Prepared:	October 19, 2022
Trade Names:	1. Aviator® Anterior Cervical Plating (ACP) System 2. LITe® Plate System 3. DynaTran™ Anterior Cervical Plating (ACP) System 4. Reflex™ Hybrid ACP System 5. UniVise™ Spinous Process Fixation Plate
Common Name:	1. Aviator® Anterior Cervical Plate System 2. LITe® Plate System Appliance, fixation, spinal intervertebral body 3. DynaTran™ Anterior Cervical Plate System 4. Reflex™ Hybrid Anterior Cervical Plate System 5. UniVise™ Spinous Process Fixation Plate Spinous Process Fixation Plate
Proposed Class:	Class II
Classification Name:	1. Aviator® Spinal intervertebral body fixation orthosis; 21 CFR §888.3060 2. LITe® Plate System Spinal intervertebral body fixation orthosis; 21 CFR §888.3060 3. DynaTran™ Spinal intervertebral body fixation orthosis; 21 CFR §888.3060 4. Reflex™ Hybrid Spinal intervertebral body fixation orthosis; 21 CFR §888.3060 5. UniVise™ Spinous Process Fixation Plate Spinal interlaminal fixation orthosis; 21 CFR §888.3050
Product Code:	1. Aviator® KWQ 2. LITe® Plate System KWQ 3. DynaTran™ KWQ

510(k) Summary: Stryker Spine Plate Systems	
	4. Reflex™ Hybrid KWQ 5. UniVise™ Spinous Process Fixation Plate PEK
Predicate Devices:	**Primary Predicate:** Aviator® (K142237) **Additional Predicates:** LITe® Plate System (K150449) DynaTran™ (K083020) Reflex™ Hybrid (K062310, K063430) UniVise™ Spinous Process Fixation Plate (K132968) PYRENEES, BLUE RIDGE and OZARK Cervical Plate Systems and the CAYMAN Thoracolumbar and Buttress Plate Systems (K182473)
Device Description:	The previously cleared devices consist of a variety of plate systems designed to provide support across implanted levels in the cervical, thoracolumbar, and lumbosacral spine until fusion is achieved. The primary purpose of this submission is to establish an MR Conditional labeling claim for these implants.
Intended Use:	**Aviator®** The Aviator® Anterior Cervical Plating System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications: • Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies) • Trauma (including fractures) • Tumors • Deformities or curvatures (including kyphosis, lordosis, or scoliosis) • Pseudarthrosis • Failed previous fusion • Decompression of the spinal cord following total or partial cervical vertebrectomy • Spondylolisthesis • Spinal stenosis **LITe® Plate System** The LITe® Plate System Universal, Sacral, 2 Screw and 4 Screw Plates are indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of the thoracic and thoracolumbar (T1-L5) spine or via an anterior approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine. The system is intended to provide additional support during fusion in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

510(k) Summary: Stryker Spine Plate Systems	
	• Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); • Pseudoarthrosis; • Spondylolysis; • Spondylolisthesis; • Spinal stenosis; • Tumors; • Trauma (i.e. Fractures or Dislocation) • Deformities (i.e. Scoliosis, Kyphosis or Lordosis) • Failed Previous Fusion The LITe® Plate System Buttress Plate is intended to stabilize the allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications. **DynaTran™** The DynaTran™ Anterior Cervical Plating System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications: • Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies) • Trauma (including fractures) • Tumors • Deformities or curvatures (including kyphosis, lordosis, or scoliosis) • Pseudarthrosis • Failed previous fusion • Decompression of the spinal cord following total or partial cervical vertebrectomy • Spondylolisthesis • Spinal stenosis **Reflex™ Hybrid** The Reflex™ Hybrid ACP System is intended for anterior intervertebral screw fixation of the cervical spine from C2 – T1. These systems are indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications: • Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies) • Decompression of the spinal cord following total or partial cervical vertebrectomy

510(k) Summary: Stryker Spine Plate Systems	
	• Trauma (including fractures) • Tumors • Deformities or curvatures (including kyphosis, lordosis or scoliosis) • Pseudoarthrosis • Failed previous fusions • Spondylolisthesis • Spinal stenosis **UniVise™ Spinous Process Fixation Plate** The UniVise™ Spinous Process Fixation Plate is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (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); and/or tumor. The UniVise™ Spinous Process Fixation Plate is intended for use with bone graft and not intended for stand-alone use.
Summary of the Technological Characteristics	The devices in this submission possess the same technological characteristics as their predicate devices; no changes have been made to any of the devices. Therefore, the fundamental scientific technology of the subject devices is the same as previously cleared devices.
Summary of the Performance Data	MR Compatibility testing per ASTM F2503 was performed. The test results demonstrate that the subject devices performance met the prescribed acceptance criteria and are substantially equivalent to the predicate devices.
Conclusion	The subject devices possess the same intended use and technological characteristics as the predicate devices. Therefore, the subject devices are substantially equivalent.