



October 8, 2020

Zimmer Biomet Spine, Inc.
David Pollard
Regulatory Affairs Specialist
10225 Westmoor Drive
Westminster, Colorado 80021

Re: K202309

Trade/Device Name: Epic™ Anterior Thoracolumbar Plate System, Gallery Laminoplasty Fixation System, Conero™ Facet Screw System, Alpine XC™ Adjustable Fusion System, Aspen® MIS Fusion System, L-Plate™ MIS Fusion System

Regulation Number: Unclassified

Regulatory Class: Class II

Product Code: MRW, KWQ, NQW, KWP

Dated: August 12, 2020

Received: August 14, 2020

Dear David Pollard:

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 and Part 809); 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
Division of Spinal Devices
Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K202309

Device Name
Epic™ Anterior Thoracolumbar Plate System

Indications for Use (Describe)

The Epic Anterior Thoracolumbar Plate System is intended to provide fixation of the thoracic, lumbar, and/or sacral spine (T1-S1) as an adjunct to fusion using autograft or allograft in skeletally mature patients in the treatment of the following instabilities or deformities:

- * Degenerative Disc Disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- * Spinal Stenosis (indicated for L1-S1 only);
- * Spondylolisthesis;
- * Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- * Trauma (i.e., fracture, dislocation, or subluxation);
- * Spondylolysis;
- * Tumor;
- * Pseudoarthrosis; and/or
- * Failed previous fusion

The Epic Anterior Thoracolumbar Plate System is indicated for use via the lateral or anterolateral surgical approach for fixation of the thoracic and thoracolumbar spine, or via the anterior surgical approach for fixation of the lumbosacral spine below the bifurcation of the great vessels.

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

510(k) Number (if known)
K202309

Device Name
Gallery Laminoplasty Fixation System

Indications for Use (Describe)

The Gallery Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The Gallery Laminoplasty Fixation System holds or buttresses the allograft in place in order to prevent the allograft from expulsion or impinging on the spinal cord.

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

510(k) Number (if known)
K202309

Device Name
Concero™ Facet Screw System

Indications for Use (Describe)

The Concero Facet Screw System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from C2 to S1 for 3.5mm and 4.0mm screws and from L1 to S1 for 4.5mm screws. For transfacet fixation, the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle. The Concero Facet Screw System is indicated for treatment of any or all of the following:

- * Pseudoarthrosis and failed previous fusions;
- * Spondylolisthesis;
- * Spondylolysis;
- * Degenerative Disc Disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies;
- * Degeneration of the facets with instability and;
- * Trauma including spinal fractures and/or dislocations.

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

510(k) Number (if known)

K202309

Device Name

Alpine XC™ Adjustable Fusion System

Indications for Use (Describe)

The Zimmer Biomet Spine Spinal Fixation System is intended to be used to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The system is intended for use with autograft or allograft.

The Zimmer Biomet Spine Spinal Fixation System is intended for posterior, non-cervical (T1-S2/ilium) pedicle and non-pedicle spinal fixation, to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following instabilities or deformities: degenerative disc disease (DDD, 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); spinal stenosis; deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The Alpine XC Adjustable MIS Fusion System 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 Alpine XC Adjustable MIS Fusion System is intended for use with bone graft material, not intended for stand-alone use.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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Indications for Use

510(k) Number (if known)
K202309

Device Name
Aspen® MIS Fusion System

Indications for Use (Describe)

The Zimmer Biomet Spine Spinal Fixation System is intended to be used to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The system is intended for use with autograft or allograft.

The Zimmer Biomet Spine Spinal Fixation System is intended for posterior, non-cervical (T1-S2/ilium) pedicle and non-pedicle spinal fixation, to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following instabilities or deformities: degenerative disc disease (DDD, 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); spinal stenosis; deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The Aspen device 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 Aspen device is intended for use with bone graft material, 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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Indications for Use

510(k) Number (if known)
K202309

Device Name

L-Plate™ MIS Fusion System

Indications for Use (Describe)

The Zimmer Biomet Spine Spinal Fixation System is intended to be used to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The system is intended for use with autograft or allograft.

The Zimmer Biomet Spine Spinal Fixation System is intended for posterior, non-cervical (T1-S2/ilium) pedicle and non-pedicle spinal fixation, to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following instabilities or deformities: degenerative disc disease (DDD, 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); spinal stenosis; deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The LPlate device 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 LPlate device is intended for use with bone graft material, 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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date	August 12, 2020
Applicant/Sponsor	Zimmer Biomet Spine, Inc. 10225 Westmoor Dr. Westminster, CO 80021
Contact Person	David Pollard Regulatory Affairs Specialist Phone: 303.253.0056
Alternate Contact	Alex Pawlowski Regulatory Affairs Project Manager Phone: 303.264.8255
Trade Name(s)	Epic™ Anterior Thoracolumbar Plate System, Gallery Laminoplasty Fixation System, Concero™ Facet Screw System, Alpine XC™ Adjustable Fusion System, Aspen® MIS Fusion System, L-Plate™ MIS Fusion System
Common Name	Spinal Fixation System
Device Class	Class II
Classification Name	MRW – System, Facet Screw Spinal Device (Unclassified)- KWQ – Appliance, Fixation, Spinal Intervertebral Body (21 CFR 888.3060) NQW – Orthosis, Spine, Plate, Laminoplasty, Metal (21 CFR 888.3050) KWP – Appliance, Fixation, Spinal Interlaminar (21 CFR 888.3050)
Device Panel	Orthopedic

Device Description & Technological Characteristics:

The Zimmer Biomet Spine *Miscellaneous Spinal Fixation Systems* referred to in this submission include the following systems: Epic, Gallery, Concero, Alpine XC, Aspen and L-Plate. These subject *Miscellaneous Spinal Fixation Systems* are identical to the predicate *Miscellaneous Spinal Fixation Systems*, Epic, Gallery, Concero, Alpine XC, Aspen and L-Plate, currently marketed. As defined within the product-specific Indications for Use, the subject *Miscellaneous Spinal Fixation Systems* are intended for the stabilization and immobilization of spinal segments as an adjunct to fusion in the cervical, thoracic, lumbar and/or sacral spine.

Predicate Devices:

The predicate devices for this submission are the currently marketed Zimmer Biomet Spine Miscellaneous Spinal Fixation Systems, Epic Gallery, Concero, Alpine XC, Aspen and L-Plate. See Table 7-1 below for how each subject device brand corresponds to the predicate device under the same brand name.

Table 7-1: Predicate Zimmer Biomet Spine Miscellaneous Spinal Fixation Systems

Subject Device Product Name (Common)	Name (Common)	Predicate FDA 510(k) Number
Epic	Epic	K092765
Gallery	Gallery	K100805
Concero	Concero	K101364
Alpine XC	Alpine XC	K131156
Aspen	Aspen	K131156
L-Plate	L-Plate	K131156

Summary of Technological Characteristics:

The technological characteristics of the subject *Miscellaneous Spinal Fixation Systems* remain identical to the currently marketed Zimmer Biomet Spine *Miscellaneous Spinal Fixation Systems* (Epic, Gallery, Concero, Alpine XC, Aspen and L-Plate) in regards to intended use, indications for use, manufacturing methods, fundamental technology, and operational principles. The only changes made to the *Miscellaneous Spinal Fixation Systems*, which are not subject of this submission, have been made via Letters-To-File. A summary of these changes subject to Letters-To-File and the technological characteristics of each Zimmer Biomet Spine *Miscellaneous Spinal Fixation Systems* can be found in **Section 13 – Device Description**. The purpose of this submission is to seek clearance for modified product labeling of the subject systems by establishing the safety and compatibility of passive implants in the magnetic resonance (MR) environment.

Summary of Performance Data:

Performance testing is not necessary to evaluate the effects within magnetic fields during Magnetic Resonance Imaging (MRI) on the subject *Miscellaneous Spinal Fixation Systems*. There are no changes associated with this submission that alter the products intended use, indications for use, fundamental technology including design, materials, manufacturing methods, sterility, and operational principles. Details of the MR environment testing are discussed within **Section 19 – Electromagnetic Compatibility and Electrical Safety**.

Intended Use / Indications for Use:

Each subject Zimmer Biomet Spine Miscellaneous Spinal Fixation Systems' Indications for Use are unchanged from the predicate devices' previous clearances (Section 6 – Indications for Use).

Epic™ Anterior Thoracolumbar Plate System

The Epic Anterior Thoracolumbar Plate System is intended to provide fixation of the thoracic, lumbar, and/or sacral spine (T1-S1) as an adjunct to fusion using autograft or allograft in skeletally mature patients in the treatment of the following instabilities or deformities: Degenerative Disc Disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);

- Spinal Stenosis (indicated for L1-S1 only);
- Spondylolisthesis;
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- Trauma (i.e., fracture, dislocation, or subluxation);
- Spondylolysis;
- Tumor;
- Pseudoarthrosis; and/or
- Failed previous fusion

The Epic Anterior Plate System is indicated for use via the lateral or anterolateral surgical approach for fixation of the thoracic and thoracolumbar spine, or via the anterior surgical approach for fixation of the lumbosacral spine below the bifurcation of the great vessels.

Gallery Laminoplasty Fixation System

The Gallery Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The Gallery Laminoplasty Fixation System holds or buttresses the allograft in place in order to prevent the allograft from expulsion or impinging on the spinal cord.

Concerto™ Facet Screw System

The Concerto Facet Screw System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from C2 to S1 for 3.5 mm and 4.0 mm screws and from L1 to S1 for 4.5 mm screws. For transfacet fixation, the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle. The Concerto Facet Screw System is indicated for treatment of any or all of the following:

- Pseudoarthrosis and failed previous fusions;
- Spondylolisthesis;
- Spondylolysis;
- Degenerative Disc Disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies;
- Degeneration of the facets with instability and;
- Trauma including spinal fractures and/or dislocations.

Alpine XC™ Adjustable Fusion System

The Zimmer Biomet Spine Spinal Fixation System is intended to be used to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The system is intended for use with autograft or allograft. The Zimmer Biomet Spine Spinal Fixation System is intended for posterior, non-cervical (T1-S2/ilium) pedicle and non-pedicle spinal fixation, to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following instabilities or deformities: degenerative disc disease (DDD, 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); spinal stenosis; deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The Alpine XC Adjustable MIS Fusion System 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 Alpine XC Adjustable MIS Fusion System device is intended for use with bone graft material, not intended for stand-alone use.

Aspen® MIS Fusion System

The Zimmer Biomet Spine Spinal Fixation System is intended to be used to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The system is intended for use with autograft or allograft. The Zimmer Biomet Spine Spinal Fixation System is intended for posterior, non-cervical (T1-S2/ilium) pedicle and non-pedicle spinal fixation, to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following instabilities or deformities: degenerative disc disease (DDD, 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); spinal stenosis; deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The Aspen device 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 Aspen device is intended for use with bone graft material, not intended for stand-alone use.

L-Plate™ MIS Fusion System

The Zimmer Biomet Spine Spinal Fixation System is intended to be used to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The system is intended for use with autograft or allograft.

The Zimmer Biomet Spine Spinal Fixation System is intended for posterior, non-cervical (T1-S2/ilium) pedicle and non-pedicle spinal fixation, to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following instabilities or deformities: degenerative disc disease (DDD, 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); spinal stenosis; deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The LPlate device 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 LPlate device is intended for use with bone graft material, not intended for stand-alone use.

Substantial Equivalence Conclusion:

The Zimmer Biomet Miscellaneous Spinal Fixation Systems, as spinal fixation devices, are substantially equivalent to the currently marketed predicate Miscellaneous Spinal Fixation Systems in regards to intended use, indications for use, fundamental technology including design, materials, manufacturing methods, sterility, and operational principles, as they are identical systems. Each of the subject systems are unchanged from the predicate versions of each respective system.