February 11, 2022

Orthofix US LLC
Jacki Koch
Principle Regulatory Affairs
3451 Plano Parkway
Lewisville, Texas 75056

Re: K211712
Trade/Device Name: 3 Anterior Cervical Plating System, Reliant Anterior Cervical Plating System, Unity Lumbosacral Fixation System, Hallmark Anterior Plate System, NewBridge Laminoplasty Fixation System, CETRA Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ, NQW
Dated: January 4, 2022
Received: January 10, 2022

Dear Jacki Koch:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211712

Device Name
3° Anterior Cervical Plating System

Indications for Use *(Describe)*
The 3° Anterior Cervical Plating System is intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies).
2. Spondylolisthesis
3. Fracture
4. Spinal stenosis
5. Deformities (i.e., scoliosis, kyphosis, and/or lordosis)
6. Tumor
7. Pseudoarthrosis
8. Revision of previous surgery

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.

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

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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211712

Device Name
Reliant Anterior Cervical Plating System

Indications for Use *(Describe)*
The Reliant Anterior Cervical Plating System is intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:
1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies).
2. Spondylolisthesis
3. Fracture
4. Spinal stenosis
5. Deformities (i.e., scoliosis, kyphosis, and/or lordosis)
6. Tumor
7. Pseudoarthrosis
8. Revision of previous surgery

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

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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)*
K211712

Device Name
Unity Lumbosacral Fixation System

Indications for Use *(Describe)*
The Unity Lumbosacral Fixation Plate is indicated for use as an anteriorly placed supplemental fixation device for the lumbosacral (L5-S1) level below the bifurcation of the vascular structures. The Unity LX Lumbar Fixation Plate is indicated for use as an anteriorly or anterolaterally placed supplemental fixation device for the lumbar region of the spine above the bifurcation of the vascular structures. When properly used, the system will help provide temporary stabilization until a solid spinal fusion develops. Specific indications include:
1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies).
2. Pseudoarthrosis.
3. Spondylolysis.
4. Spondylolisthesis.
5. Fracture.
6. Neoplastic disease.
7. Unsuccessful previous fusion surgery.
8. Lordotic deformities of the spine.
9. Idiopathic thoracolumbar or lumbar scoliosis.
10. Deformities (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomenigocele.
11. Neuromuscular deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with pelvic obliquity.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211712

Device Name
Hallmark Anterior Plate System

Indications for Use *(Describe)*
The Hallmark Anterior Plate System is a temporary implant intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies).
2. Spondylolisthesis
3. Fracture
4. Spinal stenosis
5. Deformities (i.e., scoliosis, kyphosis, and/or lordosis)
6. Tumor
7. Pseudoarthrosis
8. Revision of previous surgery

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211712

Device Name
NewBridge Laminoplasty Fixation System

Indications for Use *(Describe)*
The NewBridge Laminoplasty Fixation System is indicated for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The system holds or buttresses the allograft in place in order to prevent expulsion of the allograft or impingement of 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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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)*
K211712

Device Name
CETRA Anterior Cervical Plate System

Indications for Use *(Describe)*
The CETRA Anterior Cervical Plate System is a temporary implant intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies).
2. Spondylolisthesis
3. Fracture
4. Spinal stenosis
5. Deformities (i.e., scoliosis, kyphosis, and/or lordosis)
6. Tumor
7. Pseudoarthrosis
8. Revision of previous surgery

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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ORTHOFIX

510(k) SUMMARY

3° Anterior Cervical Plating System
Reliant Anterior Cervical Plating System
Unity Lumbosacral Fixation System
Hallmark Anterior Plate System
NewBridge Laminoplasty Fixation System
CETRA Anterior Cervical Plate System

510(k) Owner Information

Name: Orthofix US LLC
Address: 3451 Plano Parkway
Lewisville, TX 75056

Telephone Number: 214-937-2100
Fax Number: 214-937-3322
Email: jackikoch@orthofix.com

Registration Number: 2183449

Contact Person: Jacki Koch, Regulatory Affairs Program Manager

Date Prepared: February 10, 2022

Name of Device

Trade Name / Proprietary Name:

3° Anterior Cervical Plating System
Reliant Anterior Cervical Plating System
Unity Lumbosacral Fixation System
Hallmark Anterior Plate System
NewBridge Laminoplasty Fixation System
CETRA Anterior Cervical Plate System

Product Code(s):

System Name	Product Codes
3° Anterior Cervical Plating System	KWQ
Reliant Anterior Cervical Plating System	KWQ
Unity Lumbosacral Fixation System	KWQ
Hallmark Anterior Plate System	KWQ
NewBridge Laminoplasty Fixation System	NQW
CETRA Anterior Cervical Plate System	KWQ

Classification Name(s)

System Name	Classification Name
3° Anterior Cervical Plating System	Spinal Intervertebral Body Fixation Orthosis
Reliant Anterior Cervical Plating System	Spinal Intervertebral Body Fixation Orthosis
Unity Lumbosacral Fixation System	Spinal Intervertebral Body Fixation Orthosis
Hallmark Anterior Plate System	Spinal Intervertebral Body Fixation Orthosis
NewBridge Laminoplasty Fixation System	Spinal Interlaminal Fixation Orthosis

CETRA Anterior Cervical Plate System	Spinal Intervertebral Body Fixation Orthosis

Device Classification

System Name	Product Codes
3° Anterior Cervical Plating System	Class II per 21 CFR § 888.3060
Reliant Anterior Cervical Plating System	Class II per 21 CFR § 888.3060
Unity Lumbosacral Fixation System	Class II per 21 CFR § 888.3060
Hallmark Anterior Plate System	Class II per 21 CFR § 888.3060
NewBridge Laminoplasty Fixation System	Class II per 21 CFR § 888.3050
CETRA Anterior Cervical Plate System	Class II per 21 CFR § 888.3060

Review Panel: Orthopedic Device Panel

Predicate Devices: 3° Anterior Cervical Plating System (K020620)
Reliant Anterior Cervical Plating System (K030595)
Unity Lumbosacral Fixation System (K061229)
Hallmark Anterior Plate System (K100614)
NewBridge Laminoplasty Fixation System (K043338)
CETRA Anterior Cervical Plate System (K162638)

Reason for 510(k) Submission:
Orthofix is submitting this Traditional 510(k) premarket notification for the addition of MR Conditional labeling to the subject medical devices.

The subject addition of MR Conditional labeling does not change the design, intended use, materials, performance specifications or the indications for use as previously cleared.

Device Description
3° Anterior Cervical Plating System – The 3° Anterior Cervical Plating System is a temporary titanium alloy (Ti6Al-4V ELI, per ASTM F136) system comprised of a variety of non-sterile, single use components that allow the surgeon to build an anterior cervical implant construct. The system's design is intended to stabilize the cervical spinal operative site during the fusion process of a bone graft in the disc space. The system is attached to the anterior aspect of the vertebral body by means of screws to the cervical spine. The system consists of an assortment of screws, plates and associated instrumentation which assists in the surgical implantation of the devices. The system is provided non-sterile and requires sterilization prior to use.

Reliant Anterior Cervical Plating System – The Reliant Anterior Cervical Plating System is temporary, titanium alloy system comprised of a variety of single-use components that allow the surgeon to build an anterior cervical implant construct. The system is attached to the anterior aspect of the vertebral body by means of screws to the cervical spine. The system consists of an assortment of screws, plates and associated instrumentation which assist in the surgical implantation of the devices. The system is provided non-sterile and requires sterilization prior to use.

Unity Lumbosacral Fixation System – The Unity Lumbosacral Fixation System consists of the Unity 51 Lumbosacral Fixation Plate for lumbosacral fixation and the Unity LX Lumbar Fixation Plate for anterior or anterolateral fixation above L5-S1.

The Unity 51 Lumbosacral Fixation Plate is designed specifically for supplemental fixation of anterior lumbar fusions at the L5-S1 level. The plate is contoured to the unique anatomy of the L5-S1 segment. The Unity 51 Plate is available in six heights: 17mm to 25mm in 2mm increments and one additional plate at 28mm.

The Unity LX Lumbar Fixation Plate is designed for lumbar levels above L5-S1 in 2 configurations – anterior and anterolateral. In the anterolateral configuration, the plate allows surgeons lateral-to-medial placement of the self-neuro foramen. The Unity LX Plate is available in six heights: 19mm to 25mm in 2mm increments and two additional plates at 28mm and 31mm.

Hallmark Anterior Plate System – The Hallmark Anterior Plate System is comprised of a variety of non-sterile, single use, titanium alloy (6AL-4V-ELI, per ASTM F136) components that allow a surgeon to build an anterior cervical implant construct. The system is attached to the anterior aspect of the vertebral body by means of screws to the cervical spine. The system consists of an assortment of screws, plates and associated instrumentation, which assists in the surgical implantation of the devices.

NewBridge Laminoplasty Fixation System – The NewBridge Laminoplasty Fixation System is a device comprised of non-sterile, single use, titanium and titanium alloy components. The specially shaped plates, made of commercially pure (CP) titanium conforming to ASTM F67, are designed to fit the anatomy of a dorsally elevated lamina. The plates have screw holes on both ends, which allow for attachment to the vertebral body, and a screw hole in the center for attachment to the allograft.

The screws, made of titanium alloy (Ti-6Al-4V ELI, per ASTM F136) are available in a variety of lengths and diameters in order to meet individual anatomical requirements.

The NewBridge Laminoplasty Fixation System must always be used with an allograft.

CETRA Anterior Cervical Plate System – The CETRA Anterior Cervical Plate System is comprised of an assortment of non-sterile, single use, titanium alloy (Ti-6Al-4V ELI per ASTM F136) plates and screws that allow a surgeon to build a temporary anterior cervical implant construct. The plate is attached to the anterior aspect of the vertebral body, by means of screws to the cervical spine. The system includes the necessary instrumentation to assist in the surgical implantation of the devices.

Intended Use / Indications for Use

3° Anterior Cervical Plating System

The 3° Anterior Cervical Plating System is intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies).
2. Spondylolisthesis
3. Fracture
4. Spinal stenosis
5. Deformities (i.e., scoliosis, kyphosis, and/or lordosis)
6. Tumor
7. Pseudoarthrosis
8. Revision of previous surgery

Reliant Anterior Cervical Plating System

The Reliant Anterior Cervical Plating System is intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies).
2. Spondylolisthesis
3. Fracture

4. Spinal stenosis
5. Deformities (i.e., scoliosis, kyphosis, and/or lordosis)
6. Tumor
7. Pseudoarthrosis
8. Revision of previous surgery

Unity Lumbosacral Fixation System

The Unity Lumbosacral Fixation Plate is indicated for use as an anteriorly placed supplemental fixation device for the lumbosacral (L5-S1) level below the bifurcation of the vascular structures. The Unity LX Lumbar Fixation Plate is indicated for use as an anteriorly or anterolaterally placed supplemental fixation device for the lumbar region of the spine above the bifurcation of the vascular structures. When properly used, the system will help provide temporary stabilization until a solid spinal fusion develops. Specific indications include:

1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies).
2. Pseudoarthrosis.
3. Spondylolysis.
4. Spondylolisthesis.
5. Fracture.
6. Neoplastic disease.
7. Unsuccessful previous fusion surgery.
8. Lordotic deformities of the spine.
9. Idiopathic thoracolumbar or lumbar scoliosis.
10. Deformities (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomenigocele.
11. Neuromuscular deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with pelvic obliquity.

Hallmark Anterior Plate System

The Hallmark Anterior Plate System is a temporary implant intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies).
2. Spondylolisthesis
3. Fracture
4. Spinal stenosis
5. Deformities (i.e., scoliosis, kyphosis, and/or lordosis)
6. Tumor
7. Pseudoarthrosis
8. Revision of previous surgery

NewBridge Laminoplasty Fixation System

The NewBridge Laminoplasty Fixation System is indicated for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The system holds or buttresses the allograft in place in order to prevent expulsion of the allograft or impingement of the spinal cord.

CETRA Anterior Cervical Plate System

The CETRA Anterior Cervical Plate System is a temporary implant intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies).
2. Spondylolisthesis
3. Fracture

4. Spinal stenosis
5. Deformities (i.e., scoliosis, kyphosis, and/or lordosis)
6. Tumor
7. Pseudoarthrosis
8. Revision of previous surgery

Summary of the Technological Characteristics of the Device Compared to the Selected Predicate Devices

The Technological Characteristics, design, dimensions, intended use, materials and performance characteristics of the subject devices are unchanged from their previous clearance. The purpose of this 510(k) submission is for the addition of MR Conditional to the device labeling.

PERFORMANCE DATA – Summary of Non-Clinical Test Conducted for Determination of Substantial Equivalence

In accordance to the FDA Guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" the following testing was conducted:

- ASTM F2052-15 – Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment
- ASTM F2213-17 – Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment
- ASTM F2119-07 – Standard test method for evaluation of MR image artifacts from passive implants
- ASTM F2182-19E2 - Standard test method for measurement of radio frequency induced heating on or near passive implant during magnetic resonance imaging

Basis of Substantial Equivalence

As stated throughout this 510(k) notification, there are no modifications to the design, intended use, or indications for use. The purpose of this 510(k) notification is for the addition of MR Conditional labeling for the subject devices.

The subject devices are temporary, multiple component systems comprised of a variety of single use components, made of titanium alloy. There have been no changes to the design, to the material, intended use or indications for use.

Therefore, the subject devices are identical to themselves as previously cleared.

In accordance with FDA Guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment," the following testing was conducted to determine that the subject devices met requirements necessary for MRI Conditional labeling:

- ASTM F2052-15 **-** "Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment"
- ASTM F2213-17 **-** "Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment"
- ASTM F2119-07 - "Standard test method for evaluation of MR image artifacts from passive implants"
- ASTM F2182-19E2 **-** "Standard test method for measurement of radio frequency induced heating on or near passive implant during magnetic resonance imaging"
- ASTM F2503 **-** "Standard practice for marking medical devices and other items for safety in the magnetic resonance environment"