

**Axle<sup>®</sup>**  
**Interspinous Fusion System**

**510(K) Letters**

K101471	Axle original submission
K112592	Axle PEEK Insert
K130438	Axle-X plates and additional Axle plate lengths



K101471

Axle Interspinous Fusion System

**510(k) Summary****ADMINISTRATIVE INFORMATION**

NOV 24 2010

Manufacturer Name: X-spine Systems, Inc.  
452 Alexandersville Rd.  
Miamisburg, OH 45342

Telephone (937) 847-8400  
FAX (937) 847-8410

Official Contact: David Kirschman, M.D.  
Chief Medical Officer

Date Prepared: May 26, 2010

**DEVICE NAME**

Trade/Proprietary Name: Axle™ Interspinous Fusion System  
Common Name: Interspinous Process Fixation System  
Classification Name: Spinal Interlaminar Fixation Orthosis  
Device Class: Class II  
Classification: §888.3050  
Product Code: KWP

**ESTABLISHMENT REGISTRATION NUMBER**

X-spine Systems, Inc. has submitted an Establishment Registration to FDA. The Establishment Registration number is 3005031160. The owner/operator number for X-spine Systems, Inc. is 9063903.

**INTENDED USE**

The Axle Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1 inclusive). 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 Axle Interspinous Fusion System is intended for use with bone graft material, and not for stand-alone use.

## DEVICE DESCRIPTION

The Axle Interspinous Fusion System consists of plates and inserts of various sizes that are used to provide supplemental stabilization of the spinous processes to support fusion. The system components can be assembled in a variety of configurations so that adaptations can be made to take into account pathology and individual patient anatomy. The implant components are provided clean and non-sterile.

## EQUIVALENCE TO MARKETED PRODUCT

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Axle Interspinous Fusion System is substantially equivalent to the Medtronic CD Horizon Spinal System (K091445), specifically the Medtronic SPIRE Spinous Process Plate component, based on a technological comparison including the following characteristics:

- FDA Product Code
- Intended Uses
- Surgical Approach
- Anatomical Region
- Implant Materials
- Product Dimensions
- Mechanical Performance

## PERFORMANCE DATA

The implant components were tested using the following standards:

ASTM F1717 – *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*

- Static Compression Bending
- Static Torsion
- Fatigue Compression Bending

In conclusion, biomechanical testing results indicate that the Axle Interspinous Fusion System is substantially equivalent to predicate device performance and is capable of safely and effectively performing in accordance with its intended use.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-O66-0609  
Silver Spring, MD 20993-0002

X-spine Systems, Inc.  
% David Kirschman, M.D.  
Chief Medical Officer  
452 Alexandersville Rd.  
Miamisburg, Ohio 45342

NOV 24 2010

Re: K101471

Trade/Device Name: Axle Interspinous Fusion System  
Regulation Number: 21 CFR 888.3050  
Regulation Name: Spinal interlaminar fixation orthosis  
Regulatory Class: Class II  
Product Code: KWP  
Dated: November 10, 2010  
Received: November 12, 2010

Dear Dr. Kirschman:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
And Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Indications for Use - REVISED

NOV 24 2010

510(k) Number (if known): K101471

Device Name: Axle™ Interspinous Fusion System

Indications for Use:

The Axle Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1 inclusive). 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 Axle Interspinous Fusion System is intended for use with bone graft material, and not for stand-alone use.


Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K101471

DEC - 5 2011

**510(k) Summary****ADMINISTRATIVE INFORMATION**

Manufacturer Name: X-spine Systems, Inc.  
452 Alexandersville Rd.  
Miamisburg, OH 45342

Telephone (937) 847-8400  
FAX (937) 847-8410

Official Contact: David Kirschman, MD  
Chief Medical Officer

Date Prepared: September 6, 2011

**DEVICE NAME**

Trade/Proprietary Name: Axle PEEK Interspinous Fusion System  
Common Name(s): Interspinous Process Fixation System  
Classification Name(s): Spinal Interlaminar Fixation Orthosis  
Device Class: Class II  
Classification(s): §888.3050  
Product Codes(s): KWP

**ESTABLISHMENT REGISTRATION NUMBER**

X-spine Systems, Inc. has submitted an Establishment Registration to FDA. The Establishment Registration number is 3005031160. The owner/operator number for X-spine Systems, Inc. is 9063903.

**INTENDED USE**

The Axle PEEK Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1 inclusive). 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 Axle PEEK Interspinous Fusion System is intended for use with bone graft material, and not for stand-alone use.

## DEVICE DESCRIPTION

The Axle PEEK Interspinous Fusion System consists of plates and inserts of various sizes that are used to provide supplemental stabilization of the spinous processes to support fusion. The system components can be assembled in a variety of configurations so that adaptations can be made to take into account pathology and individual patient anatomy. The implant components are provided clean and non-sterile.

The plate components of the device are made from titanium alloy per ASTM F136 and the insert components are made from polyetheretherketone (Invibio PEEK-Optima LT1).

## COMPARISON TO CLEARED DEVICE

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Axle PEEK Interspinous Fusion System substantially meets the performance criteria established by the cleared parent device. The modified device is substantially equivalent to predicate device based on a comparison including the following characteristics:

- FDA Product Code
- Intended Uses
- Surgical Approach
- Anatomical Region
- Product Dimensions
- Mechanical Performance

## PERFORMANCE DATA

The implant components were tested using the following standards:

ASTM F1717 – *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*

- Static Compression Bending
- Static Torsion
- Fatigue Compression Bending

In conclusion, biomechanical testing results indicate that the Axle PEEK Interspinous Fusion System is substantially equivalent to predicate device performance and is capable of safely and effectively performing in accordance with its intended use.





Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - W066-G609  
Silver Spring, MD 20993-0002

DEC - 5 2011

X-spine Systems, Inc.  
% David Kirschman, MD  
Chief Medical Officer  
452 Alexandersville Road  
Miamisburg, Ohio 45342

Re: K112592

Trade/Device Name: Axle PEEK Interspinous Fusion System  
Regulation Number: 21 CFR 888.3050  
Regulation Name: Spinal interlaminar fixation orthosis  
Regulatory Class: Class II  
Product Code: KWP  
Dated: November 04, 2011  
Received: November 07, 2011

Dear Dr. Kirschman:

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. 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.

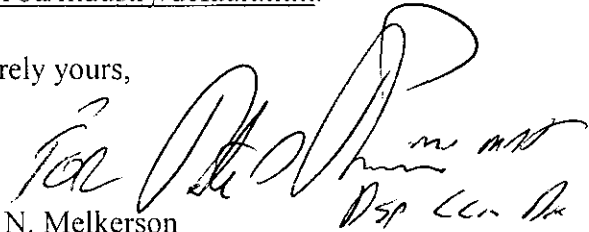
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with some additional scribbles and initials to the right.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K112592

Device Name: Axle PEEK Interspinous Fusion System

### Indications for Use:


The Axle PEEK Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1 inclusive). 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 Axle PEEK Interspinous Fusion System is intended for use with bone graft material, and not for stand-alone use.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

\_\_\_\_\_  
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number   K112592



June 27, 2013

X-Spine Systems, Incorporated  
% David Kirschman, M.D.  
Chief Medical Officer  
452 Alexandersville Road  
Miamisburg, Ohio 45342

Re: K130438

Trade/Device Name: Axle™ Interspinous Fusion System  
Regulation Number: 21 CFR 888.3050  
Regulation Name: Spinal interlaminar fixation orthosis  
Regulatory Class: Class II  
Product Code: PEK  
Dated: May 30, 2013  
Received: May 31, 2013

Dear Dr. Kirschman:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

For **Erin L. Keith**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known):   K130438  

Device Name: Axle™ Interspinous Fusion System

Indications for Use:

The Axle Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1 inclusive). 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 Axle Interspinous Fusion System is intended for use with bone graft material, and not for stand-alone use.

Prescription Use	<u>    X    </u>	AND/OR	Over-The-Counter Use
<u>          </u>			
(Part 21 CFR 801 Subpart D)			(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Ronald P. Jean -S**

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(Division Sign-Off)  
 Division of Orthopedic Devices  
 510(k) Number: K130438