April 10, 2018

Axis Orthopaedics
% Mr. Steve Brown
QA/RA Manager
CoorsTek Medical
560 West Golf Course Road
Providence, Utah 84332

Re: K180301
Trade/Device Name: AXIS 5.5 Lumbar Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: April 3, 2018
Received: April 5, 2018

Dear Mr. Brown:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K180301

Device Name
Axis 5.5 Lumbar Pedicle Screw System

Indications for Use *(Describe)*
The AXIS 5.5 LUMBAR PEDICLE SCREW SYSTEM is intended for posterior, non-cervical fixation of skeletally mature patients as an adjunct to fusion for the following indications: 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); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

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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510(k) SUMMARY

Device Trade Name: AXIS 5.5 Lumbar Pedicle Screw System

Date: April 10, 2018
Sponsor: Axis Orthopaedics

Contact Person: Steve Brown

Manufacturer: Axis Orthopaedics
Common Name: Axis 5.5 Lumbar Pedicle Screw System
Device Classification: Class II
Classification Name: Thoracolumbosacral Pedicle Screw System
Regulation: 888.3070

Device Regulation Panel: **Orthopedic**

Device Product Code: **NKB**

Device Description:
The AXIS 5.5 LUMBAR PEDICLE SCEW System consists of a variety of shapes and sizes of rods, screws, Crosslink plates, which can be rigidly locked into a variety of configurations, with each construct being tailormade for the individual case.

The AXIS 5.5 LUMBAR PEDICLE SCEW System implant components are fabricated from medical grade titanium alloy described by such standards as ASTM F67 or ASTM F136 or ISO 5832-3 or 5832-2. Axis Orthopaedics Corporation expressly warrants that these devices are fabricated from one of the foregoing material specifications. No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

To achieve best results, do not use any of the AXIS 5.5 LUMBAR PEDICLE SCEW System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another Axis Orthopaedics' document. As with all orthopaedic and neurosurgical implants, none of the AXIS 5.5 LUMBAR PEDICLE SCEW System components should ever be reused under any circumstances.

Indications for Use:
The AXIS 5.5 LUMBAR PEDICLE SCREW SYSTEM is intended for posterior, non-cervical fixation of skeletally mature patients as an adjunct to fusion for the following indications: 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); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

Implant
Materials

Material:	Standard:
Ti-6Al-4V ELI	ASTM F136-13

Technological Characteristics:
There are no technological characteristics that raise new issues of safety or effectiveness.

Assessment of performance data:

The AXIS Orthopaedics 5.5 Lumbar Pedicle Screw system was designed as an adjunct to fusion in the lower spine. The objective of this testing was to demonstrate that the subject AXIS device is equivalent to predicate devices with respect to testing recommended in ASTM F1717-15.

Mechanical testing on the subject device was performed per the applicable standards referenced above and according to test report 1297-9997-001-01 (protocol included). The respective data is presented in full in Appendices of the report. A comparison of the provided data to published data in the discussion/conclusion section shows that the subject preforms at an acceptable level.

Based on the above information, it can be concluded that the subject device is substantially equivalent with respect to its mechanical performance.

Legally Marketed Predicate Devices:
Primary:
Medtronic CD Horizon Spinal System (K042167)
Predicate Indications for Use:
Primary:
Medtronic (K042167)- The CD HORIZON® Spinal System is intended for posterior, non-cervical fixation for the following indications: 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); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

Based upon the similarities of the Axis 5.5 Lumbar Pedicle Screw System and the predicate devices studied, the safety and effectiveness of the Axis 5.5 Lumbar Pedicle Screw System is substantially equivalent to the predicate devices referenced.

Purpose:
The purpose of this Traditional 510(k) submission is to gain clearance for the Axis 5.5 Lumbar Pedicle Screw System