May 20, 2020

Axis Spine Technologies Ltd
Mr. Edwin Lindsay
QA/RA Consultant
Suite 204, 54-56 Victoria Street
St. Albans, AL1 3HZ
United Kingdom

Re: K200352
Trade/Device Name: Axis Spine Technologies ALIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: March 3, 2020
Received: March 11, 2020

Dear Mr. Lindsay:

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,

Brent Showalter, Ph.D.
Assistant Director (Acting)
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)*
K200352

Device Name
Axis Spine Technologies ALIF

Indications for Use *(Describe)*

The ALIF System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment prior to treatment with the devices. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

The ALIF System must be used with supplemental internal spinal fixation systems (i.e. posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine.

For use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate 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.

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Axis Spine Technologies Ltd.
Traditional 510(k)

For Axis Spine Technologies ALIF

510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's Name:

Axis Spine Technologies Ltd

Submitter's Address:

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Edwin Lindsay
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Date Prepared:

19th May 2020

Axis Spine Technologies Ltd.
Traditional 510(k)

For Axis Spine Technologies ALIF

Below summaries the Device Classification Information regarding the Axis Spine Technologies ALIF:

Primary Product Code:

Regulation Number	Device	Device Class	Product Code	Classification Panel
883.3080	Axis Spine ALIF	2	OVD	Orthopedic

Device Trade Name:

Axis Spine Technologies ALIF

Device Common Name:

Intervertebral Body Fusion Device

Intended/ Indications Use:

The ALIF System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to -S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment prior to treatment with the devices. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

The ALIF System must be used with supplemental internal spinal fixation systems (i.e. posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine.

For use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

Summary of Substantial Equivalence:

The following predicate devices have been chosen that the Axis Spine Technologies ALIF can claim equivalence with, and these are detailed below:

- **Primary Predicate:**

  K132596 - Custom Spine Optimus ALIF System

- **Additional Predicate:**

  K170592 - NuVasive BASE Interfixated Titanium System

Any technical differences have been justified, both scientifically and using performance testing. These do not affect the safety or effectiveness of the proposed device.

Axis Spine Technologies Ltd.
Traditional 510(k)

For Axis Spine Technologies ALIF

Device Description:

The Axis Spine Technologies ALIF is an inter-fixated interbody system consisting of a modular interbody spacer manufactured from Ti6Al4V. The system is designed to be assembled in vivo. The spacer comprises of two endplates and a central core. Each component is available in a variety of shapes and sizes to allow the assembled device to suit the individual pathology and anatomical conditions of the patient.

The Axis Spine Technologies ALIF System intervertebral fusion device is designed to address lumbar pathologies utilizing placement through an anterior approach. The device's hollow core or graft aperture allows for packing of autogenous and/or allogeneic bone graft to help promote a solid fusion. A rough surface on the device endplates serves to grip the adjacent vertebrae to resist migration and expulsion of the device. The subject device is indicated for use with supplemental internal spinal fixation (i.e., posterior pedicle screw and rod system).

The Axis Spine Technologies ALIF implant is composed of:

- one (1) inferior endplate manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 and ISO 5832-3.
- one (1) inferior endplate manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 and ISO 5832-3.
- one (1) core manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 and ISO 5832-3.
- three (3) bone screws manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 and ISO 5832-3.
- one (1) cover plate manufactured from PEEK-Optima HA Enhanced.

Technological Characteristics:

As was established in this submission, the subject Axis Spine Technologies ALIF is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States.

The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, function, and range of sizes.

Non-Clinical Tests (Performance/Physical Data):

Nonclinical testing was performed to demonstrate that the subject BASE Interfixated Titanium System is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic compression testing per ASTM F2077
- Static and dynamic compression shear testing per ASTM F2077
- Subsidence testing per ASTM F2267
- Expulsion and Axial Pushout of Retention Device testing

The results of these studies show that the Axis Spine Technologies ALIF meets or exceeds the performance of the predicate device and does not introduce any new risks; therefore, the system is substantially equivalent to the predicate device.

Animal Studies

No animal studies were conducted as part of submission to prove substantial equivalence.

Axis Spine Technologies Ltd.
Traditional 510(k)

For Axis Spine Technologies ALIF

Clinical Studies

No clinical studies were conducted as part of submission to prove substantial equivalence.

Safety and Effectiveness/Conclusion:

Based on the information presented in these 510(k) premarket notifications the Axis Spine Technologies ALIF is considered substantially equivalent. The Axis Spine Technologies ALIF is as safe and effective as the currently marketed predicate devices.

Based on testing and comparison with the predicate devices, the Axis Spine Technologies ALIF indicated no adverse indications or results. It is our determination that the Axis Spine Technologies ALIF is safe, effective and performs within its design specifications and is substantially equivalent to the predicate device.