Atlas Spine, Inc.
% Ms. Meredith May
VP, Empirical Consulting, LLC
Empirical Consulting, LLC
4628 Northpark Drive
Colorado Springs, Colorado 80918

June 14, 2018

Re: K180675
Trade/Device Name: Atlas Spine Expandable Cervical Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: May 30, 2018
Received: May 30, 2018

Dear Ms. May:

This letter corrects our substantially equivalent letter of June 13, 2018.

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 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 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,

Brent Showalter -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)*
K180675

Device Name

Atlas Spine Expandable Cervical Interbody System

Indications for Use *(Describe)*

The Atlas Spine Expandable Cervical Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Atlas Spine Expandable Cervical Interbody System is intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation. The System is designed 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.

510(k) Summary

Applicant/Sponsor: Atlas Spine, Inc.
1555 Jupiter Park Drive, Suite 4
Jupiter, FL, 33458
(561) 741-1108

Contact Person: Meredith May
Empirical Consulting, LLC
4628 Northpark Drive
Colorado Springs, CO 80918
(719) 264-9937

Proposed Trade Name: Atlas Spine Expandable Cervical Interbody System

Common Name: Intervertebral body fusion device

Classification Name: Intervertebral Fusion Device with Bone Graft, Cervical
(21 CFR 888.3080)

Device Class: Orthopedics panel Class II device

Device Product Code: ODP

Predicate Devices:

Primary:	NuVasive CoRoent Small Interbody System (K163491)
Additional:	Orthofix CONSTRUX™ MINI Peek Ti Spacer System (K121649)
Additional:	Southern Spine C-Fuse PEEk Cervical Fusion System (K130948)
Additional:	Atlas Spine Expandable Interbody System (K162918)

Device Description:

The Atlas Spine Expandable Cervical Interbody System consists of various size and style options to address the clinical and anatomic needs of individual patients. The implant is rectangular in its general shape with the capability to expand in height. The implant incorporates bone graft cavities through the superior and inferior surfaces to allow fusion between adjacent vertebral bodies. The implants incorporate a textured bone contacting surface to resist migration/expulsion of the implant post operatively. Additionally, the implant incorporates an opening posteriorly to allow the addition of bone graft post expansion.

The implants components are manufactured from implantable grade Ti6Al4V per ASTM F136 alloy and Peek Optima LT1 delivered in the pre-assembled, unexpanded state.

Indications for Use:

The Atlas Spine Expandable Cervical Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Atlas Spine Expandable Cervical System is intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myclopathy, and/or pain at mulitple contiguous levels from C2 - T1. This system is intended to be used with supplemental fixation. The System is designed for use with autogenous and/ or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

Substantial Equivalence

The Atlas Spine Expandable Cervical Interbody System has the same intended use, indications for use and similar manufacturing materials as the predicate device(s). The range of sizes of the Atlas Spine Expandable Interbody System is similar to the predicate device(s).

Non-Clinical Testing

The Atlas Spine Expandable Cervical Interbody System was evaluated as recommended in FDA's *Guidance for Industry and FDA Staff: Class II Special controls guidance document: Intervertebral body Fusion Device,* dated June 12, 2007.

Bench testing was performed and consisted of the following test methods per ASTM F2077 and ASTM F2267:

- Static testing in a load to failure mode in axial compression,
- Static testing in a load to failure mode in shear,
- Static testing in a load to failure mode in torsion,
- Static testing in expulsion,
- Static testing in subsidence,
- Dynamic axial compression testing to estimate the maximum run out load
- Dynamic compression shear testing to estimate the maximum run out load
- Dynamic torsion testing to estimate the maximum run out load

Test results demonstrated that the Atlas Spine Expandable Cervical Interbody System is found to be substantially equivalent to the predicate

Clinical Performance Data Summary

No clinical testing was required.

Conclusion

Based upon similarities in design, materials, intended use, indications for use and the results of mechanical testing, the Atlas Spine Expandable Cervical Interbody System is substantially equivalent to the predicate devices.