DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 9, 2017

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

Re: K162918
Trade/Device Name: Atlas Spine Expandable Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: January 10, 2017
Received: January 12, 2017

Dear Ms. May:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K162918

Device Name

Atlas Spine Expandable Interbody System

Indications for Use *(Describe)*

The Atlas Spine Expandable Interbody System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved levels. These patients may have had a previous non-fusion surgery at the involved level(s).

The Atlas Spine Expandable Interbody System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft; and supplemental fixation system (i.e. Firebird® Spinal Fixation System).

Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the Atlas Spine Expandable Interbody System.

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

| | |
|---|---|
| **Applicant/Sponsor:** | Atlas Spine, Inc.<br>1555 Jupiter Park Drive, Suite 4<br>Jupiter, FL, 33458<br>(561) 741-1108 |
| **Contact Person:** | Meredith May<br>Empirical Consulting, LLC<br>4628 Northpark Drive<br>Colorado Springs, CO 80918<br>(719) 264-9937 |
| **Date:** | January 10, 2017 |
| **Proposed Trade Name:** | Atlas Spine Expandable Interbody System |
| **Common Name:** | Intervertebral body fusion device |
| **Classification Name:** | Intervertebral fusion device with bone graft, lumbar per 21 CFR 888.3080. This falls under the Orthopedics panel/87 as a Class II device. |
| **Device Product Code:** | MAX |
| **Predicate Devices:** | Caliber™ Spacer (K102293) - Primary<br>ProLift® Expandable System (K153400) - Additional<br>FORZA® PTC Spacer System (K152475) - Additional<br>Spinal Jaxx Interbody Fusion Device (K152501) - Ref<br>L-Varlock Lumbar Cage (K080537) - Ref<br>Atlas Spine Verterbral Body Replacement (K063205) - Ref<br>Bluefin™ Interbody System (K143479) - Ref<br>Dorado™ Intervertebral Body Cage (K091638 & K072289) - Ref |

## Device Description:

The Atlas Spine Expandable 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 infinitely within its design limitations. 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 material post expansion.

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

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## Summary of Technological Characteristics

The Atlas Spine Expandable 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 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:

- Static testing in a load to failure mode in axial compression,
- Static testing in a load to failure mode in shear,
- 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

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

## 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 Interbody System is substantially equivalent to the predicate devices.