July 15, 2026

Atlas Spine, Inc.
Patrick Kennedy
Director, RA/QA
1555 Jupiter Park Dr., Suite 1
Jupiter, Florida 33458

Re: K252822
Trade/Device Name: Atlas Spine HiRISE™ Expandable Cervical-p Corpectomy Implant
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: PLR
Dated: June 29, 2026
Received: June 29, 2026

Dear Patrick Kennedy:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252822

Please provide the device trade name(s).

Atlas Spine HiRISE™ Expandable Cervical-p Corpectomy Implant

Please provide your Indications for Use below.

The Atlas Spine HiRISE™ Expandable Cervical-p Corpectomy Implant is indicated for vertebral body replacement in the cervical spine (C2-T1). The implant is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion.

When used in the cervical spine (C2-T1), Atlas Spine HiRISE™ Expandable Cervical-p Corpectomy implants are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in the cervical degenerative disorders. These implants are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion. The implant is intended to be used with supplemental fixation that has been cleared by the FDA for use in the cervical spine.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

510(k) #: K252822

510(k) Summary

Prepared on: 2026-07-14

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Atlas Spine, Inc.
Applicant Address	1555 Jupiter Park Drive, Suite 1 Jupiter FL 33458 United States
Applicant Contact Telephone	561.346.6466
Applicant Contact	Mr. Patrick Kennedy
Applicant Contact Email	pkennedy@atlasspine.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Atlas Spine HiRISE™ Expandable Cervical-p Corpectomy Implant
Common Name	Spinal intervertebral body fixation orthosis
Classification Name	Spinal Vertebral Body Replacement Device - Cervical
Regulation Number	888.3060
Product Code(s)	PLR

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K252560	Atlas Spine HiRISE Expandable Cervical Corpectomy System	PLR
K180675	HiJAK™ Expandable Cervical Interbody System	ODP
K192570	Atlas Spine Expandable Cervical Standalone Interbody System	OVE

Device Description Summary

21 CFR 807.92(a)(4)

The Atlas Spine HiRISE™ Expandable Cervical-p Corpectomy Implant is comprised of an assortment of non-sterile, single use, titanium alloy (Ti6Al4V ELI per ASTM F136) implants with height expansion capability. The expandable implant is inserted into the cervical spine and expanded to fit the patient anatomy.

The Atlas Spine HiRISE™ Expandable Cervical-p Corpectomy implants are offered with integrated fixation and bone screws and without integrated fixation. The implants feature adjustable lordotic configurations to help restore the natural curvature of the spine. The implants can be used in an anterior cervical corpectomy as a vertebral body replacement (VBR).

The implants feature anti-migration teeth on both the inferior and superior surfaces to provide increased stability and help prevent anterior/posterior movement of the device.

The Atlas Spine HiRISE™ Expandable Cervical-p Corpectomy Implant is not intended to be used as a stand-alone device. The implant must be used with a supplemental fixation system and is provided non-sterile and requires sterilization prior to use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Atlas Spine HiRISE™ Expandable Cervical-p Corpectomy Implant is indicated for vertebral body replacement in the cervical spine (C2-T1). The implant is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion.

When used in the cervical spine (C2-T1), Atlas Spine HiRISE™ Expandable Cervical-p Corpectomy implants are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in the cervical degenerative disorders. These implants are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion. The implant is intended to be used with supplemental fixation that has been cleared by the FDA for use in the cervical spine.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The HiRISE™ Expandable Cervical-p Corpectomy Implant has the same intended use and indications for use as the predicate device(s).

Technological Comparison

21 CFR 807.92(a)(6)

The HiRISE™ Expandable Cervical-p Corpectomy Implant has similar device design and manufacturing materials as the predicate device(s). The range of sizes of the HiRISE™ Expandable Cervical-p Corpectomy Implant is similar to the predicate device(s).

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

An engineering rationale and confirmatory ASTM F2077 Dynamic Axial Compression & Torsion Testing demonstrated that the subject device is not a new worst-case design.

Based upon similarities in design, materials, intended use, indications for use and the results of non-clinical testing, the Atlas Spine HiRISE™ Expandable Cervical-p Corpectomy Implant is substantially equivalent to previously cleared predicate devices.