October 20, 2025

ALLUMIN8, Inc.
℅ Jessica Czamanski, BSBME, MSBME, RAC
Regulatory, Quality, and Compliance Consultant
DuVal & Associates, P.A.
Suite 1820, Medical Art Building, 825 Nicollet Mall
Minneapolis, MN 55402

Re: K242827
Trade/Device Name: A8 INTEGR8™ Porous Pedicle Screws
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: May 7, 2025
Received: May 8, 2025

Dear Jessica Czamanski, BSBME, MSBME, RAC:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Colin O'neill -S

Colin O'Neill, M.B.E.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242827

Device Name
A8 INTEGR8™ Porous Pedicle Screw System

Indications for Use *(Describe)*
ALLUMIN8® A8 INTEGR8™ porous pedicle screws are intended to immobilize and stabilize spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system to treat the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

1. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies);
2. Spondylolisthesis;
3. Trauma (i.e., fracture or dislocation);
4. Spinal stenosis;
5. Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
6. Spinal Tumor;
7. Pseudoarthrosis; and
8. Failed previous fusion.

When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, the implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the ALLUMIN8® A8 INTEGR8™ porous pedicle screws are intended to treat pediatric patients diagnosed with spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudoarthrosis, and/or failed previous fusion. Pediatric pedicle screw fixation is limited to a posterior approach.

ALLUMIN8® A8 INTEGR8™ Porous Pedicle Screws are intended to be used with autograft or allograft.

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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K242827 510(K) SUMMARY

Submitter's Name:	ALLUMIN8, Inc.
Submitter's Address:	3158 W. Lakefront Court Springfield, Missouri 65810
Submitter's Telephone:	417-689-2424
Contact Person:	Jessica Czamanski, MS, RAC Regulatory, Quality, and Compliance Consultant DuVal & Associates, P.A. 1-754-422-9101 jczamanski@duvalfdalaw.com
Date Summary was Prepared:	10/08/25
Trade or Proprietary Name:	A8 INTEGR8™ Porous Pedicle Screw System
Device Classification Name:	Thoracolumbosacral Pedicle Screw System
Classification & Regulation #:	Class II per 21 CFR §888.3070
Product Code:	NKB
Classification Panel:	Orthopedic – Spinal (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The A8 INTEGR8™ Porous Pedicle Screw System is a thoracolumbosacral pedicle screw system containing implants intended to provide immobilization and stabilization of spinal segments. The system consists of porous additively manufactured (AM) pedicle screws and machined polyaxial tulip assemblies and machined rods.

Immobilization and stabilization are achieved by connecting each spinal segment which have affixed pedicle screws with the spinal rods.

Components are offered in various shapes and sizes to meet the requirements of the individual patient anatomy. The pedicle screw shafts are made from Ti-6Al-4V ELI per ASTM F3001. All other implant components (tulips, saddle, locking ring, and rods) are machined.

The rods are offered in various diameters and lengths to accommodate individual patient anatomy. The rods are available in straight or pre-lordosed curvature to meet patient anatomical needs and are manufactured from either Ti-6Al-4V ELI or Co-28Cr-6Mo.

INDICATIONS FOR USE

ALLUMIN8® A8 INTEGR8™ porous pedicle screws are intended to immobilize and stabilize spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system to treat the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

1. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies);
2. Spondylolisthesis;

3. Trauma (i.e., fracture or dislocation);
4. Spinal stenosis;
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6. Spinal Tumor;
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ALLUMIN8® A8 INTEGR8™ Porous Pedicle Screws are intended to be used with autograft or allograft.

TECHNOLOGICAL CHARACTERISTICS

The predicates included in this submission were selected based on the best practices described in the FDA Draft Guidance document *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission*. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism
- Components and Sizes

Predicate Devices

510k #	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K200303	Reform Pedicle Screw System	Precision Spine, Inc.	NKB, KWP	Primary
K202498	4CIS SARA Spine System, 4CIS VERTU Spine System	Solco Biomedical Company India Private Limited	NKB	Additional
K190360	LineSider Spinal System	Integrity Implants Inc.	NKB, KWP	Additional

The subject screw shaft is additively manufactured from Ti-6Al-4V ELI per ASTM F3001. Predicates could not be identified which used additively manufactured screws. The technological differences between the subject and predicate devices do not raise any different questions for safety and effectiveness. The subject AM screws have been mechanically tested to show substantial equivalence to subtractive machined predicate pedicle screws.

PERFORMANCE DATA

The A8 INTEGR8™ Porous Pedicle Screws has been tested in the following test modes:

- Static & dynamic compression bending per ASTM F1717-21
- Static torsion per ASTM F1717-21
- Static and dynamic testing per ASTM F2193-20

- Static and dynamic testing per ASTM F1798-21
- Screw strength and pullout tests per ASTM F543-17
- Finite Element Analysis of ASTM 2193

The results of this non-clinical testing show that the strength of the A8 INTEGR8™ Porous Pedicle Screw System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices. Although the trade name includes the term “porous”, the device design does not meet FDA’s current regulatory definition for a porous coating. The term “porous” in this context is reflective of the device’s Gaussian topography (a controlled three-dimensional surface architecture based on Gaussian curvature bone morphology) and is not intended to imply any performance characteristics.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the A8 INTEGR8™ Porous Pedicle Screw System is substantially equivalent to the predicate device. The mechanical performance for the A8 INTEGR8™ Porous Pedicle Screw System demonstrated comparable strength and endurance to FDA cleared pedicle screw systems.