Innovasis, Inc.
Mr. Michael Thomas
Director Regulatory Affairs
614 E 3900 S
Salt Lake City, Utah 84107

May 20, 2024

Re: K241276
Trade/Device Name: Vector™ Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: May 2, 2024
Received: May 6, 2024

Dear Mr. Michael Thomas:

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.

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2024.05.20 11:57:54 -04'00'

for

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241276

Device Name

Vector™ Pedicle Screw System

Indications for Use *(Describe)*

When used for posterior pedicle screw or posterior non-pedicle fixation, the Innovasis Vector™ Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (DDD – defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture, dislocation, failed previous fusion (pseudoarthrosis), and/or tumor resection.

When used for posterior non-cervical screw fixation in pediatric patients, the Innovasis Vector Pedicle Screw System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis (AIS). Additionally, the Innovasis Vector Pedicle Screw System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, and fracture caused by tumor and/or trauma. Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/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.

510(k) Summary

Prepared on: 2024-05-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Innovasis, Inc.
Applicant Address	614 E 3900 S Salt Lake City UT 84107 United States
Applicant Contact Telephone	801-261-2236
Applicant Contact	Mr. Michael Thomas
Applicant Contact Email	MThomas@Innovasis.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Vector™ Pedicle Screw System
Common Name	Thoracolumbosacral pedicle screw system
Classification Name	Thoracolumbosacral Pedicle Screw System
Regulation Number	888.3070
Product Code(s)	NKB, KWP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K102248	Excella II® Spinal System	NKB
K140238	Excella III-D® Spinal Deformity System	NKB
K161014	Nuvasive® Reline® System	NKB

Device Description Summary

21 CFR 807.92(a)(4)

The Vector™ Pedicle Screw System is a thoracolumbar system composed of polyaxial pedicle screws, rods, hooks, rod-to-rod connectors, locking caps, lateral connectors, and transverse cross links. The system is designed with multiple options to address complex, multi-level deformity cases and accommodate various patient anatomies. The Vector Pedicle Screw System is also designed to facilitate percutaneous screw and rod placement via Minimally Invasive Surgery (MIS). The cannulated pedicle screws and extended reduction tabs allow for rod placement and minimal tissue disruption. The system was designed to minimize the number and complexity of procedural steps. Implants are manufactured from Titanium (Ti-6Al-4V ELI) per ASTM F136 or Cobalt Crome (CoCr) per ASTM F562.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

When used for posterior pedicle screw or posterior non-pedicle fixation, the Innovasis Vector™ Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (DDD – defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture, dislocation, failed previous fusion (pseudoarthrosis), and/or tumor resection.

When used for posterior non-cervical screw fixation in pediatric patients, the Innovasis Vector Pedicle Screw System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis (AIS). Additionally, the Innovasis Vector Pedicle Screw System is intended to

treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, and fracture caused by tumor and/or trauma. Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device has substantially equivalent indications for use as the primary predicate device K102248 (Excella II® Spinal System) and additional predicate devices K140238 (Excella III-D® Spinal Deformity System), K161014 (Nuvasive® Reline® System).

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has substantially equivalent technological characteristics (i.e., design, material, chemical composition, principle of operation) as the primary predicate device K102248 (Excella II® Spinal System) and additional predicate devices K140238 (Excella III-D® Spinal Deformity System), K161014 (Nuvasive® Reline® System).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following tests were performed on worst case components from the subject Vector™ Pedicle Screw System:
Static and Dynamic Compression Bending per ASTM F1717
Static Torsion per ASTM F1717
Static Axial and Torsional Grip per ASTM F1798

N/A - no clinical data were necessary.

All testing performed demonstrated substantially equivalent mechanical performance to legally marketed predicate devices.

The data submitted in this 510(k) submission demonstrates the substantial equivalence of the subject Vector™ Pedicle Screw System as compared to the predicates identified.