Pantheon Spinal
℅ Daniel Johnson
Regulatory Engineer
DJJ Consulting LLC
425 Literary Rd Suite 401
Cleveland, Ohio 44113

July 26, 2024

Re: K241494
Trade/Device Name: Pantheon Pedicle Screw and Iliac Bolt Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ, OUR
Dated: May 24, 2024
Received: May 28, 2024

Dear Daniel Johnson:

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: 2024.07.26 15:15:28 -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.

510(k) Number *(if known)*
K241494

Device Name
Pantheon Pedicle Screw and Iliac Bolt Fixation System

Indications for Use *(Describe)*
The Pantheon Pedicle Screw System is intended to provide immobilization and stabilization of the spine in skeletally mature patients as an adjunct to fusion for procedures of the thoracic, lumbar, and sacral spine (T1-S1). This system is intended for anterior/anterolateral non-pedicle fixation, posterior non-pedicle fixation, and posterior pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

The Pantheon Iliac Bolt Fixation System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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.

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Pedicle Screw & Iliac Bolt Fixation System
510(k) Summary

Submitted By:	Pantheon Spinal 40132 Industrial Park Cir. Suite #101 Georgetown, TX 78626
Date:	07/26/2024
Contact Person:	Daniel Johnson, Regulatory Consultant
Contact Telephone:	(216) 333-2127
Device Trade Name:	Pedicle Screw and Iliac Bolt Fixation System
Common Name:	Pedicle Screw Spinal System
Classification Name:	Thoracolumbosacral Pedicle Screw System, Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis, Smooth or Threaded Metallic Bone Fixation Fastener
Regulation Number:	21 CFR Section 888.3070, 888.3050, 888.3060, 888.3040
Reviewing Panel:	Orthopedic
Product Codes:	NKB, KWP, KWQ, OUR
Primary Predicate:	Talon Spinal System (K102995)
Reference Predicate:	Outlet Sacroiliac Joint Fusion System (K181881)

Device Description:

The Pantheon Pedicle Screw Fixation System is a top loading, multiple component, posterior spinal fixation system which consists of pedicle screws, rods, hooks, and cross links that are used for attachment to the non-cervical spine (the thoracic spine through the sacrum and in the ilium). Implant components are available in a variety of sizes so that constructs may be assembled to suit the individual pathology and anatomy of the patient. Rods span the distance between screws and achieve fixation by the mechanical joining of the rods with screws.

The Pantheon Iliac Bolt Fixation System has threaded screw implants with dual helix threads designed to be able to screw into pre-drilled bone in the sacrum. Implant components are available in a variety of sizes so that constructs may be assembled to suit the individual pathology and anatomy of the patient. Optional lag rings are also available.

Screws, rods, cross links, and other implant components are made from titanium alloy (Ti-6Al-4V) conforming to ASTM F136 or ISO 5832-3. Additionally, some rods may be manufactured from cobalt-chrome alloy (Co-Cr) conforming to ASTM F1537 or ISO 5832-12.

Indications for Use:

The Pantheon Pedicle Screw System is intended to provide immobilization and stabilization of the spine in skeletally mature patients as an adjunct to fusion for procedures of the thoracic, lumbar, and sacral spine (T1-S1). This system is intended for anterior/anterolateral non-pedicle fixation, posterior non-pedicle fixation, and posterior pedicle fixation for the following indications:

degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

The Pantheon Iliac Bolt Fixation System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Summary Statements:

The subject device indications are the same as the predicate device indications.

The subject and predicate devices have the same technological characteristics.

Mechanical performance testing of the Pantheon Pedicle Screw and Iliac Bolt System was evaluated based on the Guidance for Industry and FDA Staff, Spinal System 510(k)s. The Pedicle Screw System was evaluated per ASTM F1717 and ASTM F1798. The Iliac Bolt Fixation System was evaluated per ASTM F2193 and ASTM F543. No clinical testing is being submitted with the 510(k). The results and analysis of the Pantheon Pedicle Screw and Iliac Bolt Fixation performance testing demonstrate that the subject and predicate devices are substantially equivalent.

Conclusion: The subject device is substantially equivalent to the predicate devices.