November 8, 2024

Jeil Medical Corporation
Jinwoo Kim Kim
RA Specialist
702•703•704•705•706•804•805•807•812•815-ho, 55
Digital-ro 34-gil, Guro-gu
Seoul, 08378
Korea, South

Re: K243004
Trade/Device Name: Xpine Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: September 26, 2024
Received: September 26, 2024

Dear Jinwoo Kim Kim:

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,

RYAN TROMBETTA -S

Digitally signed by RYAN TROMBETTA -S
Date: 2024.11.08 14:11:02 -05'00'

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)*

K243004

Device Name

Xpine Spinal Fixation System

Indications for Use *(Describe)*

Xpine Spinal Fixation 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 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
• failed previous fusion

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

K243004
Prepared on November 5, 2024

1. Contact Details [21 CFR 807.92(a)(1)]

- Applicant Name: Jeil Medical Corporation
- Applicant Address: 702•703•704•705•706•804•805•807•812•815-ho, 55, Digital-ro 34-gil, Guro-gu, Seoul, 08378, Republic of Korea
- Applicant Contact Telephone: +82 2 850 3934
- Applicant Contact: Ms. Jinwoo Kim
- Applicant Contact Email: jinwookim@jeilmed.co.kr

2. Device Name [21 CFR 807.92(a)(2)]

- Device Trade Name: Xpine Spinal Fixation System
- Common Name: Thoracolumbosacral pedicle screw system
- Classification Name: Thoracolumbosacral Pedicle Screw System
- Regulation Number: 888.3070
- Product Code(s): NKB

3. Legally Marketed Predicate Devices [21 CFR 807.92(a)(3)]

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K142381	Xia® 3 Spinal System	NKB
K231887	ARIX Ankle Distal Tibia System (Reference Device)	HRS

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4. Device Description Summary [21 CFR 807.92(a)(4)]

The Xpine Spinal Fixation System, Internal Fixation Device for Spinal Surgery, is comprised of: Pedicle Screw, Set Screw, Rod, and Cross Link. Various forms and sizes of these implants are available to consider the unique pathology of individual patients for purposes of stabilization, or corrective action through the application of force. Components are made of Ti6Al4V ELI, a titanium-based alloy, which complies with ASTM F136.

5. Intended Use/Indications for Use [21 CFR 807.92(a)(5)]

Xpine Spinal Fixation 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 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
- failed previous fusion

6. Indications for Use Comparison [21 CFR 807.92(a)(5)]

The difference in indications for use between the subject and the predicate device (Xia® 3 Spinal System) is that the subject device is only intended to be used as a non-cervical pedicle screw system in adult patients, while the predicate device is not only used as that but intended to be used as an anterior/anterolateral, non-pedicle screw, and in pediatric patients also. This difference does not constitute a new intended use.

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7. Technological Comparison [21 CFR 807.92(a)(6)]

Based on the technological feature comparison, the subject device was found to have no significant differences between the subject device and predicate devices that would adversely affect the use of the product, and it is substantially equivalent to the predicate device in technological characteristics.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)
The subject device and predicate device are the Thoracolumbosacral Pedicle Screw System. Both are made of Titanium Alloy (ASTM F136), and provided non-sterile. Detailed design/dimension would not be the same, but equivalent.

Bench tests were conducted to demonstrate substantial equivalence to the predicate device. The tests were conducted according to the following standards:

- ASTM F1717, Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
- Static and dynamic axial compression bending testing
- Static torsion testing

Clinical data is not applicable.

Bench tests were conducted for the subject device according to ASTM F1717. All test results were higher than the acceptance criteria from the reference literature. Therefore, substantially equivalent mechanical performance with the predicate device has been demonstrated.

Based on the indications for use, technological characteristics, bench testing, and comparison with the predicate device, the subject device has demonstrated substantial equivalence for its intended use.