Innosys Co., Ltd.
Hye-Kyung Lee
RA Specialist
20, Sandan-ro 76beon-gil(Rd)
Uijeongbu-si, Gyeonggi-do 11781
Korea, South

October 26, 2023

Re: K231737
Trade/Device Name: ANAX™ 5.5 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: September 26, 2023
Received: September 27, 2023

Dear Hye-Kyung Lee:

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: 2023.10.26 12:29:22 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231737

Device Name
ANAX™ 5.5 Spinal System

Indications for Use *(Describe)*
The ANAX™ 5.5 SPINAL SYSTEM is a posterior, non cervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally-mature patients as an adjunct to fusion by autogenous bone graft in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar and sacral spine:

- Spondylolisthesis (Grade 3 and 4)
- Degenerative spondylolisthesis with objective evidence of neurological impairment
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or 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

Manufacturer: Innosys Co., Ltd.
20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, Korea, 11781

Sponsor: Innosys Co., Ltd.
20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, Korea, 11781

Sponsor Contact: Hye-Kyung Lee, Regulatory Affairs Specialist
+82 31-860-6839
hklee@inno-sys.net

Date Prepared: **June 12, 2023**

Device Name: Trade Name: ANAX™ 5.5 Spinal System

Classification Name: Thoracolumbosacral Pedicle Screw System, per 21 CFR 888.3070

Common Name: Thoracolumbosacral Pedicle Screw System

Product Code: NKB

Primary Predicate Device: ANAX™ 5.5 Spinal System (K173524, K162189, K143417, K132101)

Additional Predicates: OPTIMA™ Spinal System(K024096)
Synergy™ Spinal System - Synergy VLS Screw(K011437)
Fixpine II System(K100765)

Description of Device:

The ANAX™ 5.5 Spinal System is manufactured by Innosys Co., Ltd.. The ANAX™ 5.5 Spinal System is a top-loading multiple component, posterior spinal fixation system and minimally invasive surgery system which consist of pedicle screws, rods, set screws, connectors and a transverse (cross) linking mechanism. The ANAX™ 5.5 Spinal System allows surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The ANAX™ 5.5 Spinal System components are supplied non-sterile, single use and are fabricated from medical grade titanium alloy (ASTM F136) and medical grade cobalt-chromium-molybdenum alloy (ASTM F1537). All pedicle screws have self-tapping function in ANAX™ 5.5 Spinal System The double

lead thread is applied to the all pedicle screws to shorten the operation time. ANAX™ 5.5 Spinal System with CoCr rods may be used to provide immobilization and stabilization of spinal segment when the rigid system is need. (Recommendation: trauma or deformities) The product life time of ANAX™ 5.5 Spinal System is 2 years based on mechanical test result. The purpose of this submission is to add uniplanar screws and connectors to the ANAX™ 5.5 Spinal System.

Indications for Use:

ANAX™ 5.5 Spinal System is a posterior, noncervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally-mature patients as an adjunct to fusion by autogenous bone graft in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar and sacral spine:

- Spondylolisthesis (Grade 3 and 4)
- Degenerative spondylolisthesis with objective evidence of neurological impairment
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

Substantial Equivalence:

ANAX™ 5.5 Spinal System is substantially equivalent to the ANAX™ 5.5 Spinal System (K173524, K162189, K143417, K132101) in design, material, mechanical performance, function and intended use.

The mechanical performance of ANAX™ 5.5 Spinal System met the acceptance criteria which have been established from the predicate device.

1. Comparison Technological Characteristics

The predicate and proposed device have the similar intended use and basic fundamental scientific technology and share the following similarities;

- Same indications for use
- Similar design features
- Incorporate the same materials
- Equivalent mechanical performance

2. Performance Testing

The mechanical strength evaluation was conducted to compare data of the proposed device of the ANAX™ 5.5 Spinal System and predicate device (K173524, K162189, K143417, K132101) to verify there are no new safety and effectiveness issues were not raised by the proposed device. The data meet all acceptance criteria and verify that the performance of the ANAX™ 5.5 Spinal System is substantially equivalent to the predicate device.

The following tests were performed:

(1) Static compression bending test according to ASTM F1717
(2) Static torsion test according to ASTM F1717
(3) Compression bending fatigue test according to ASTM F1717
(4) Axial gripping capacity test according to ASTM F1798
(5) Axial torque gripping capacity test according to ASTM F1798

3. Conclusion

The data and information provided in this submission support the conclusion that the ANAX™ 5.5 Spinal System is substantially equivalent to its predicate device with respect to indications for use and technological characteristics.