July 24, 2026

MANTIZ Co., Ltd.
Jay Kim
Senior Researcher
423-15, Hyeoksin-Daero
Daegu, Dong 41701
Republic Of Korea

Re: K260362
Trade/Device Name: QUATTRO Spinal system (Open Configuration); QUATTRO-GADGET Spinal system (MIS Configuration)
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: July 7, 2026
Received: July 7, 2026

Dear Jay 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260362

Please provide the device trade name(s).

QUATTRO Spinal system (Open Configuration);
QUATTRO-GADGET Spinal system (MIS Configuration)

Please provide your Indications for Use below.

The QUATTRO Spinal System are intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications:

• Degenerative disc disease (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 and pseudarthrosis

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K260362

510(k) Summary

Prepared on: 2026-07-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	MANTIZ Co.,Ltd.
Applicant Address	423-15, Hyeoksin-daero Daegu Dong-gu 41071 Korea, Republic of
Applicant Contact Telephone	82 10 6680 8429
Applicant Contact	Mr. Jay Kim
Applicant Contact Email	kim.hj@mantiz.net

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	QUATTRO Spinal system (Open Configuration); QUATTRO-GADGET Spinal system (MIS Configuration)
Common Name	Thoracolumbosacral pedicle screw system
Classification Name	Thoracolumbosacral Pedicle Screw System
Regulation Number	888.3070
Product Code(s)	NKB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K210420	Goblin and Goblin LS Pedicle Screw Systems	NKB

Device Description Summary

21 CFR 807.92(a)(4)

The subject device is a posterior thoracolumbosacral pedicle screw spinal fixation system intended to provide temporary stabilization of spinal segments as an adjunct to spinal fusion procedures.

The system consists of multiple implant components, including pedicle screws, longitudinal rods, set screws, and optional cross-links, which are assembled intraoperatively to immobilize and stabilize the spine.

The device functions by rigidly anchoring pedicle screws into the vertebrae and mechanically coupling them with rods to restrict motion across the treated spinal segments, thereby promoting conditions favorable for fusion. The scientific principle of operation is based on mechanical load sharing and stabilization of the spinal column until solid bony fusion occurs.

The implant components are manufactured from titanium alloy materials commonly used in orthopedic spinal applications and are available in a range of sizes to accommodate patient anatomy. The system does not contain active electronic components and relies solely on mechanical fixation principles.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The QUATTRO Spinal System are intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications:

• Degenerative disc disease (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 and pseudarthrosis

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

The Subject Device has the same intended use and identical indications for use as the predicate device, Goblin and Goblin LS Pedicle Screw Systems (K210420). Both devices are intended for posterior, non-cervical pedicle fixation as an adjunct to spinal fusion in skeletally mature patients with degenerative disc disease, spondylolisthesis, trauma, spinal stenosis, spinal deformities, tumor, and pseudoarthrosis. Because the indications for use are the same, no new intended use is introduced.

Technological Comparison 21 CFR 807.92(a)(6)

The technological characteristics of the Subject Device are substantially equivalent to those of the predicate device, Goblin and Goblin LS Pedicle Screw Systems (K210420). Both systems are posterior, non-cervical pedicle screw fixation systems consisting of pedicle screws, rods, set screws, and optional transverse connectors. The design features, mechanical interface, and method of assembly are the same as those of the predicate.

Both the Subject Device and predicate device are manufactured from Ti-6Al-4V ELI in accordance with ASTM F136, and all materials used in patient-contacting components share the same chemical composition and biocompatibility profile. The devices operate under the same principle of action-rigid spinal fixation through pedicle anchorage and rod stabilization-and do not include electronics, software, biologic materials, or energy-based components.

Any dimensional variations within the screw or rod size ranges are minor and do not alter the mechanical behavior or clinical use of the system. Mechanical testing performed in accordance with ASTM F1717 (static compression bending, dynamic compression bending, and static torsion) demonstrates that the Subject Device performs at least as well as the predicate device, confirming that no new technological questions are introduced.

Therefore, the Subject Device has the same technological characteristics as the predicate device and does not raise new issues of safety or effectiveness.

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

Non-clinical bench testing was performed to support the substantial equivalence of the subject device.
Performance testing of the subject device was conducted in accordance with ASTM F1717-21, Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.

The testing evaluated the mechanical performance of the spinal fixation system under representative loading conditions.
The results of the subject device testing were compared against performance data from the legally marketed predicate device, including previously conducted dynamic compression, static torsion, and static compression testing.

These non-clinical performance evaluations demonstrated that the subject device exhibits mechanical performance comparable to that of the predicate device.

Not Applicable.

Based on the results of non-clinical bench testing conducted in accordance with ASTM F1717-21, and a comparison with performance data from the legally marketed predicate device, the subject device demonstrates mechanical performance that is as safe and effective as the predicate device.

The non-clinical performance data support the conclusion that the subject device is substantially equivalent to the predicate device for its intended use.