June 9, 2026

ChanPin MedTak Co., Ltd.
Che-Yung Kuan
R&D Manager
7F., No. 168, Lide St., Zhonghe Dist.
New Taipei City 235, Taiwan (R.O.C.)
New Taipei City, 235
Taiwan

Re: K251251
Trade/Device Name: ChanPin Pedicle Screw Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: May 11, 2026
Received: May 11, 2026

Dear Che-Yung Kuan:

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,

EILEEN CADEL -S 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

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.	K251251

Please provide the device trade name(s).

ChanPin Pedicle Screw Spinal System

Please provide your Indications for Use below.

The CHANPIN Pedicle Screw Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
A.Degenerative disc disease (defined as discogenic back pain with disc degeneration confirmed by medical history and radiographic studies)
B.Spondylolisthesis
C.Trauma
D.Tumors
E.Spinal stenosis
F.Spinal deformities or curvatures (e.g., scoliosis, kyphosis, and/or lordosis)
G.Failed previous fusion
H.Pseudarthrosis

The CHANPIN Pedicle Screw Spinal System is intended for adult patients only.

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

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

ChanPin MedTak Co., Ltd.
ChanPin Pedicle Screw Spinal System

510(k) SUMMARY

Type of Submission: Traditional

Date of Summary: 2026.05.11

Submitter: ChanPin MedTak Co., Ltd.
Address: 7F., No. 168, Lide St., Zhonghe Dist., New Taipei City 235, Taiwan (R.O.C.)
Phone: +886-2-32341185 ext 102
Contact: Mr. Che-Yung Kuan
Email kuan@cpmt.com.tw

Identification of the Device:

Proprietary/Trade Name:	ChanPin Pedicle Screw Spinal System
Regulation Description:	Thoracolumbosacral pedicle screw system
Review Panel:	Orthopedic
Regulation Number:	21 CFR 888.3070
Product Code:	NKB
Device Class:	Class II
Secondary Regulation Description:	Spinal interlaminal fixation orthosis.
Secondary Regulation Number:	21 CFR 888.3050
Secondary Product Code:	KWP
Device Class:	Class II

Identification of the Predicate Device:

Predicate Device Name:	NOVA Minimally Invasive System
Model Number:	N/A
510(k) Number:	K182416
Manufacturer:	BAUI BIOTECH CO., LTD.

ChanPin MedTak Co., Ltd.
ChanPin Pedicle Screw Spinal System

Regulation Number:	21 CFR 888.3070
Product Code:	NKB
Device Class:	Class II

Indications for Use of the Device

The CHANPIN Pedicle Screw Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

A. Degenerative disc disease (defined as discogenic back pain with disc degeneration confirmed by medical history and radiographic studies)
B. Spondylolisthesis
C. Trauma
D. Tumors
E. Spinal stenosis
F. Spinal deformities or curvatures (e.g., scoliosis, kyphosis, and/or lordosis)
G. Failed previous fusion
H. Pseudarthrosis

The CHANPIN Pedicle Screw Spinal System is intended for adult patients only.

Device Description

The ChanPin Pedicle Screw System includes three series: EZ Spine, EZ MIS, and EZ MIS Plus, specifically designed to accommodate various forms of spinal surgeries and meet diverse clinical needs. The system consists of primary components such as pedicle screws, rods, set screws, and hooks. All series are available in multiple sizes to address different surgical requirements and patient conditions. All components are manufactured from

titanium alloy (Ti-6Al-4V) compliant with ASTM F136 and ISO 5832-3 standards.

Non-clinical Testing

A series of safety and performance tests were conducted on the subject device.

- Performance tests
  - Static and dynamic axial compression bending (ASTM F1717-21)
  - Static torsion (ASTM F1717-21)
  - Twisting strength (ASTM F543-17 Annex A1)
  - Pullout strength (ASTM F543-17 Annex A3)

All the test results demonstrate ChanPin Pedicle Screw Spinal System is substantially equivalent to the predicate device.

Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

Substantial Equivalence Determination

ChanPin Pedicle Screw Spinal System is substantially equivalent in intended use, principles of operation, safety and performance to the cleared NOVA Minimally Invasive System (K182416). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

ChanPin MedTak Co., Ltd.
ChanPin Pedicle Screw Spinal System

Similarity and Difference

The subject device has similar indications for use/intended use and principle of operation as the predicate device.

The differences between the subject device and the predicate device are diameter and length of Poly-axial Screws. The subject device has tested safety and performance tests and the results were complied with the test requests. Therefore, the differences between subject device and predicate device did not raise any problems of safety or effectiveness. The subject device is substantially equivalent to the predicate device in intended use, main materials, safety and performance claims.

Conclusion

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that ChanPin Pedicle Screw Spinal System is substantially equivalent to the predicate device.