



October 24, 2025

Beijing Fule Science & Technology Development Co., Ltd.
Xiaoliang Chen
International Sales Manager
No. 50, Mafang West Industry Zone, Pinggu District
Beijing, 101101
China

Re: K252730

Trade/Device Name: Fule Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: August 28, 2025
Received: August 28, 2025

Dear Xiaoliang Chen:

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,

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.

K252730

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Please provide the device trade name(s).

?

Fule Spinal Fixation System

Please provide your Indications for Use below.

?

The Fule Spinal Fixation System is a thoracolumbosacral pedicle screw system intended to provide immobilization and stabilization of thoracic, lumbar, and sacral spinal segments (T1 to S2) as an adjunct to fusion in skeletally mature patients for the following acute and chronic instabilities or deformities: degenerative disc disease (as confirmed by patient history and radiographic studies), spondylolisthesis, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudarthrosis and failed previous fusion.

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)

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510(k) Summary

Submitted in accordance with the requirements of 21 CFR 807.92.

Applicant: BEIJING FULE SCIENCE & TECHNOLOGY DEVELOPMENT CO., LTD.

Address: NO. 50, MAFANG WEST INDUSTRY ZONE, PINGGU DISTRICT, BEIJING, CHINA

Contact Person: Xiaoliang Chen, International Sales Manager

Telephone Number: +8618210731904

Date Prepared: October 22, 2025

Device Identification

Trade Name: Fule Spinal Fixation System

Common Name: Pedicle Screw Spinal System

Regulation: 21 CFR 888.3070 – Thoracolumbosacral Pedicle Screw System

Regulatory Class: Class II

Product Code: NKB

Primary Predicate Device

Predicate Device Name: SmartLoc Spinal Fixation System

Manufacturer: A-Spine Asia Co., Ltd.

510(k) Number: K111883

Device Description

The Fule Spinal Fixation System consists of rods, polyaxial pedicle screws, set screws, and connectors, available in a range of sizes to accommodate different patient anatomies. Components are manufactured from titanium alloy (Ti6Al4V, ASTM F136) in accordance with ISO 5832-3.

Indications for Use

The Fule Spinal Fixation System is a thoracolumbosacral pedicle screw system intended to provide immobilization and stabilization of thoracic, lumbar, and sacral spinal segments (T1 to S2) as an adjunct to fusion in skeletally mature patients for the following acute and chronic instabilities or deformities: degenerative disc disease (as confirmed by patient history and radiographic studies), spondylolisthesis, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudarthrosis and failed previous fusion.

Technological Characteristics

The subject and predicate devices have the same:

- Basic design and configuration
- Materials (Ti6Al4V, ASTM F136)
- Principle of operation
- Indications for use

Minor dimensional variations (e.g., screw diameter range) do not raise new safety or effectiveness questions.

Performance Data

Nonclinical performance testing was conducted in accordance with FDA-recognized consensus standards and FDA's Spinal System 510(k) guidance:

Mechanical Testing: ASTM F1717-21 (Static compression-bending, dynamic compression-bending, static torsion). Results demonstrated that the subject device has substantially equivalent mechanical performance to the predicate device.

Substantial Equivalence Conclusion

Based on the intended use, technological characteristics, and performance data, the Fule Spinal Fixation System is substantially equivalent to the predicate SmartLoc Spinal Fixation System (K111883) and does not raise new questions of safety or effectiveness.