June 17, 2026

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

Re: K253155
Trade/Device Name: Fule Metallic Lockable Intramedullary Nail Systems
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: May 20, 2026
Received: May 20, 2026

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 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,

FARZANA SHARMIN -S

Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty 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.

510(k) Number *(if known)*
K253155

Device Name
Fule Metallic Lockable Intramedullary Nail Systems

Indications for Use *(Describe)*
The Intramedullary Nail System of The Fule Metallic Lockable Intramedullary Nail is intended to provide temporary stabilization of various types of fractures, malunions and nonunion of the tibia. The nails are inserted using an open or closed technique and can be statically, dynamically and compressed locked. It is indicated for long bone fracture fixation, specifically tibial fracture fixation, which may include the following:

- Open and closed tibial fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Nonunion and malunion.

The Fule Proximal Femoral Nail Systems (PFNA System and SISF System) of the Fule Metallic Lockable Intramedullary Nail are intended for the treatment of stable and unstable fractures of the proximal femur, including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof.

- Short nails (PFNA:170–240 mm / SISF: 180–240 mm):
- Pertrochanteric fractures
- Intertrochanteric fractures
- Basal neck fractures
- Combinations of these fracture types
- Long nails (PFNA:300–420 mm):
- Subtrochanteric fractures
- Pertrochanteric fractures associated with shaft fractures
- Pathologic fractures (including prophylactic use) in both trochanteric and diaphyseal regions
- Long subtrochanteric fractures
- Proximal or distal non-unions
- Malunions
- Revisions

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

510(k) Number: K253155

Date Prepared: 2026-06-17

1. Submitter / Applicant Information

Applicant Name:

BEIJING FULE SCIENCE & TECHNOLOGY DEVELOPMENT CO., LTD.

Applicant Address:

No. 50, Mafang West Industry Zone, Pinggu District, Beijing 101101, China

Contact Person:

Mr. Xiaoliang Chen

Telephone:

+86 18210731904

Email:

xiao.liang.c.fule@gmail.com

2. Device Information

Trade Name:

Fule Metallic Lockable Intramedullary Nail Systems

Common Name:

Intramedullary fixation rod

Classification Name:

Rod, Fixation, Intramedullary and Accessories

Regulation Number:

21 CFR 888.3020

Product Code(s):

HSB, HWC

Device Classification:

Class II

3. Legally Marketed Predicate Devices

The subject device claims substantial equivalence to the primary predicate device identified below. Other legally marketed devices are identified as additional predicate devices to support approach-specific configurations and indications.

Predicate Status	510(k) Number	Predicate Device	Product Code
Primary predicate	K200880	T2 Tibial Nailing System, T2 Femoral Nail System, T2 Supracondylar Nail System, T2 Recon Nail System, T2 Greater Trochanter Nail (GTN),T2 Ankle Arthrodesis Nail,T2 Arthrodesis Nail System	HSB
Additional predicate	K182783	DePuy Synthes Trauma Orthopedic Nail Implants / Proximal Femoral Nail System	HRS / HSB as applicable

4. Device Description

The Fule Metallic Lockable Intramedullary Nail Systems are metallic orthopedic internal fixation devices intended to provide temporary stabilization of long bone fractures by insertion of an intramedullary nail into the medullary canal. The system consists of intramedullary nails, proximal fixation components, compression nails/blades, locking heads, interlocking screws, and associated reusable surgical instruments. The devices are intended for use in skeletally mature patients.

The product family includes two device groups:

1. **Fule Intramedullary Nail System**
   This system is intended for tibial fracture fixation. It includes intramedullary nails and associated locking screws designed to provide temporary stabilization of tibial fractures, malunions, nonunions, and related long bone conditions.
2. **Fule Proximal Femoral Nail Systems, including PFNA and SISF sub-systems**
   These systems are intended for proximal femoral fracture fixation. The systems include short nail configurations and long nail configurations,

depending on the fracture indication. The proximal femoral systems include femoral nails, anti-rotation compression nails/blades or screw-type cephalomedullary elements, locking heads, and interlocking screws.

The subject implants are manufactured from titanium alloy material suitable for long-term orthopedic implantation. The devices are supplied non-sterile and are intended to be sterilized before use according to the validated sterilization instructions in the labeling.

Reusable surgical instruments associated with the system are supplied non-sterile and are packaged in protective polyethylene packaging. The packaging is intended for physical protection during shipping, storage, and handling, and is not intended to provide or maintain sterility.

5. Intended Use / Indications for Use

The Intramedullary Nail System of The Fule Metallic Lockable Intramedullary Nail is intended to provide temporary stabilization of various types of fractures, malunions and nonunion of the tibia. The nails are inserted using an open or closed technique and can be statically, dynamically and compressed locked. It is indicated for long bone fracture fixation, specifically tibial fracture fixation, which may include the following:

- Open and closed tibial fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Nonunion and malunion.

* The Fule Proximal Femoral Nail Systems (PFNA System and SISF System) of the Fule Metallic Lockable Intramedullary Nail are intended for the treatment of stable and unstable fractures of the proximal femur, including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof.

- Short nails (PFNA:170–240 mm / SISF: 180–240 mm):
  - Pertrochanteric fractures
  - Intertrochanteric fractures

- Basal neck fractures
- Combinations of these fracture types

- Long nails (PFNA:300–420 mm):
  - Subtrochanteric fractures
  - Pertrochanteric fractures associated with shaft fractures
  - Pathologic fractures (including prophylactic use) in both trochanteric and diaphyseal regions
  - Long subtrochanteric fractures
  - Proximal or distal non-unions
  - Malunions
  - Revisions

6. Technological Characteristics and Comparison to Predicate Devices

The subject devices and predicate devices have the same general intended use: temporary stabilization and fixation of bone fractures using metallic intramedullary nail constructs.

The Fule Intramedullary Nail System and the T2 Tibial Nailing System predicate are both intramedullary nail systems intended for tibial fracture fixation. Both systems use metallic intramedullary nails inserted into the medullary canal and locking screws to stabilize fractured bone segments during healing.

The Fule Proximal Femoral Nail Systems, including the PFNA and SISF sub-systems, and the K182783 predicate device are proximal femoral intramedullary nail systems intended for the treatment of stable and unstable proximal femoral fractures. Both systems use a metallic femoral nail, proximal femoral head/neck fixation components, and distal/proximal locking components to stabilize fractures during healing. The PFNA substantial equivalence comparison states that the subject and predicate devices have the same intended use and similar technological characteristics, including intramedullary nail-based fixation, titanium alloy construction, comparable dimensions, proximal femoral head/neck fixation

components, and locking screw/bolt functions.

Differences between the subject and predicate devices include dimensional ranges, titanium alloy grade, component geometry, and sub-system configurations. These differences do not introduce a new intended use, a new anatomical site, a new patient population, a new surgical approach, or a new mode of action. The differences were evaluated through dimensional comparison, material conformity evaluation, biocompatibility evaluation, and nonclinical mechanical performance testing.

7. Nonclinical Performance Testing

Nonclinical bench testing was performed using final or representative finished devices to evaluate the mechanical safety, structural integrity, fixation strength, and functional performance of the subject devices under loading modes relevant to intramedullary fixation.

The following nonclinical performance tests were conducted or relied upon:

- Static and dynamic four-point bending testing of the intramedullary nail in accordance with ASTM F1264-24
- Static torsion testing of the intramedullary nail in accordance with ASTM F1264-24
- Static and dynamic bending testing of locking screws in accordance with ASTM F1264-24
- Torsional properties, axial pullout strength, and driving torque testing of metallic interlocking screws in accordance with ASTM F543-23
- Static and dynamic axial compression bending testing of the compression nail in accordance with ASTM F384-17
- Cutout resistance testing of the compression nail using a device-specific method relevant to cephalomedullary fixation performance

The submitted nonclinical testing supports that the subject devices have adequate mechanical performance for their intended use and do not raise new or different questions of safety or effectiveness compared with the predicate devices. The

submitted supporting information identifies ASTM F1264-24, ASTM F543-23, ASTM F384-17, cutout resistance testing, instrument biocompatibility bridging, and non-sterile packaging documentation as supporting evidence.

8. Biocompatibility

The subject implants are manufactured from titanium alloy materials commonly used for long-term orthopedic implantation. Biocompatibility and material information were evaluated to support the biological safety of the patient-contacting implant materials and final finished device.

For the reusable surgical instruments, patient-contacting components are medical-grade stainless steel. The biocompatibility of the reusable surgical instruments was supported through a bridging assessment to the FDA-cleared Fule Spinal Fixation System instruments under K252730. The bridging rationale states that the patient-contacting stainless steel components are equivalent with respect to material formulation, raw material specification, processing, machining, surface finishing, cleaning, packaging configuration, and sterilization status, and that no new chemicals, additives, fillers, plasticizers, lubricants, coatings, or mold-release agents are introduced.

Based on the material information, manufacturing information, cleaning and sterilization status, and biocompatibility evaluation, the subject devices do not present new or increased biocompatibility risks compared with the predicate devices.

9. Sterilization, Cleaning, and Packaging

The subject implants and reusable surgical instruments are supplied non-sterile. The implants are single-use devices and must be sterilized before implantation according to the validated sterilization cycle specified in the labeling. The reusable instruments must be cleaned and steam sterilized prior to first use and after each use.

The reusable instruments are packaged in protective polyethylene self-sealing pouches with product identification labeling. The instrument packaging prominently identifies the non-sterile status and includes instructions to clean and sterilize before use. The packaging system is intended only to protect the instruments during transportation, storage, and handling and is not a sterile barrier system.

A product adoption rationale was provided for the cleaning validation of the reusable surgical instruments. The assessment compares the subject instruments with predicate instruments previously reviewed under K252730 and concludes that the subject instruments do not represent a new or worse cleaning challenge compared with the predicate representative instruments. The comparison addresses materials, manufacturing processes, sterilization parameters, hollow structures, assembled components, crevices, material complexity, surface area, and overall cleanability.

10. Clinical Testing

Clinical testing was not required to support substantial equivalence. The determination of substantial equivalence is supported by comparison to legally marketed predicate devices, technological comparison, material evaluation, biocompatibility evaluation, sterilization and reprocessing information, packaging information, and nonclinical performance testing.

11. Predetermined Change Control Plan

A Predetermined Change Control Plan is not included in this 510(k). Therefore, no PCCP information is applicable to this 510(k) Summary.

12. Substantial Equivalence Conclusion

The Fule Metallic Lockable Intramedullary Nail Systems and the identified predicate devices have the same intended therapeutic and surgical use, similar indications for use, similar anatomical applications, similar technological characteristics, and similar operating principles.

Any differences between the subject and predicate devices, including dimensional ranges, component geometry, sub-system configurations, and titanium alloy grade, do not introduce a new intended use, new indication, new anatomical site, new patient population, new surgical approach, or new mode of action. The differences were evaluated through material assessment, dimensional comparison, biocompatibility evaluation, sterilization and reprocessing information, packaging information, and nonclinical performance testing.

Performance testing demonstrated that the subject devices have acceptable mechanical performance for their intended use. Biocompatibility and material

information support the suitability of the subject device materials for their intended patient-contacting use. Cleaning, sterilization, and packaging information support the labeled non-sterile supply configuration and required processing before use.

Therefore, the Fule Metallic Lockable Intramedullary Nail Systems are substantially equivalent to the identified predicate device, and do not raise different questions of safety or effectiveness.