June 18, 2026

Suzhou And Science & Technology Development Corp.
Limin Zhu
Regulatory Affairs
#2 Ansheng Rd.,Hexing Jinfeng Town
Zhangjiagang, Jiangsu 215625
China

Re: K253080
Trade/Device Name: AND Medical Femoral Nail System (PFNA01); AND Medical Femoral Nail System (PFNA02)
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: May 22, 2026
Received: May 22, 2026

Dear Limin Zhu:

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.

Submission Number *(if known)*

K253080

Device Name

AND Medical Femoral Nail System (PFNA01);
AND Medical Femoral Nail System (PFNA02)

Indications for Use *(Describe)*

AND Medical Femoral Nail System is Suitable for intramedullary fixation of femoral fractures.
Indications for use of the PFNA02(Length 170 mm - 240 mm) include:
– Pertrochanteric fractures;
– Intertrochanteric fractures;
– High subtrochanteric fractures.
Indications for use of the PFNA01 (Length 320 mm - 420 mm), include:
– Low and extended subtrochanteric fractures;
– Ipsilateral trochanteric fractures;
– Combination fractures (in the proximal femur);
– Pathological fractures.

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) #: K253080

510(k) Summary

Prepared on: 2026-06-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Suzhou AND Science & Technology Development Corp.
Applicant Address	No.2 Ansheng Road,Hexing Jinfeng Town,Zhangjiagang City,Jiangsu,China Zhangjiagang Jiangsu 215625 China
Applicant Contact Telephone	+86 15190928088
Applicant Contact	Mr. zhu limin
Applicant Contact Email	Zhulimin@andtosi.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	AND Medical Femoral Nail System (PFNA01); AND Medical Femoral Nail System (PFNA02)
Common Name	Intramedullary fixation rod
Classification Name	Rod, Fixation, Intramedullary And Accessories
Regulation Number	888.3020
Product Code(s)	HSB, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K172830	Double Medical Femoral Nail System	HSB

Device Description Summary

21 CFR 807.92(a)(4)

AND Medical Femoral Nail System is made of Ti6-Al4-V material that complies with the ISO 5832-3:2016 standard. Interlocking intramedullary nails are classified into PFNA01 and PFNA02 types based on their structural type, usage site, and surgical approach. Among them, PFNA01 and PFNA02 are composed of nail, lock nail, blade nail, and extended cap. The specifications of the product are diameter x length, and the specifications of PFNA01 and PFNA02 are also divided into left/right. The product is delivered in a non-sterile state.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

AND Medical Femoral Nail System is Suitable for intramedullary fixation of femoral fractures.
Indications for use of the PFNA02(Length 170 mm - 240 mm) include:
– Pertrochanteric fractures;
– Intertrochanteric fractures;
– High subtrochanteric fractures.
Indications for use of the PFNA01 (Length 320 mm - 420 mm), include:
– Low and extended subtrochanteric fractures;
– Ipsilateral trochanteric fractures;
– Combination fractures (in the proximal femur);
– Pathological fractures.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The device has same indications for use and material in comparison to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The predict device contains two patient contact materials, Ti-6Al-4V following ISO 5832-3 or Ti-6Al-4V Eli following ASTM F 136. There is only one material of the declared product, Ti-6Al-4V following ISO 5832-3. The titanium alloy used is determined to be biocompatible and will not cause different questions of safety and effectiveness.
The proposed device is mainly different in dimension with the predicate device, but the mechanical test demonstrated the results of both devices are very similar.

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

Non-Clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device conforms to ASTM F1264-16e1 Standard Specification and Test Methods for Intramedullary Fixation Devices, ASTM F543-17 Standard Specification and Test Methods for Metallic Medical Bone Screws, ASTM F384-17 Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices, including:
- Static Four-point Bending Test of Nail
- Dynamic Four-point Bending Test of Nail
- Static Torsion Test of Nail
- Static Three-point Bending Test of Locking Screw
- Dynamic Three-point Bending Test of Locking Screw
- Insertion/removal Test of Locking Screw
- Pullout Test of Locking Screw
- Torsion Test of Locking Screw.
- Cantilever Bending Test
- Cut-out Test

Non-Clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device.
The test results demonstrated that the proposed device conforms to ASTM F1264-16e1 Standard Specification and Test Methods for Intramedullary Fixation Devices, ASTM F543-17 Standard Specification and Test Methods for Metallic Medical Bone Screws, ASTM F384-17 Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices, that demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device (K172830) identified above.