June 16, 2026

ZheJiang Decans Medical Devices Co., Ltd.
Haifeng Liu
Registration Manager
No.2836 Xincheng Avenue, Gaozhao Street, Xiuzhou District
JiaXing, Zhejiang 314031
China

Re: K253046
Trade/Device Name: HERA Interlocking Intramedullary Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: May 19, 2026
Received: May 19, 2026

Dear Haifeng Liu:

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

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.	K253046

Please provide the device trade name(s).

HERA Interlocking Intramedullary Nailing System

Please provide your Indications for Use below.

(1)Femoral Trochanteric Fixation Nail System
Femoral Trochanteric Fixation Nail System is intended use to:
a)Pertrochanteric, intertrochanteric or Subtrochanteric fractures;
b)Combination fractures of femur;
c)Pathological fractures or reconstruction following tumor resection and grafting;
d)Poor healing of fracture, including nonunions, malunions and bone lengthening or shortening;
e)Other fracture, including simple severely comminuted, spiral, long oblique and segmental fractures of femur.
(2)Antegrade Femoral Reconstruction Nail System
Antegrade Femoral Reconstruction Nail System rencon mode is intended use to Femoral shaft and neck fracture；standard mode is intended use to Femoral shaft fracture.
(3)Tibial Nail system
Tibial nail system is intended to be implanted into the medullary canal of tibia for alignment, stabilization, fixation of fractures caused by trauma or disease.

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)

510(k) Summary

Preparation Date:	June 15, 2026	
Submitter	ZheJiang Decans Medical Devices Co., Ltd. No.2836 Xincheng Avenue, Gaozhao Street, Xiuzhou District, Jiaxing City, Zhejiang Province, 314031,P.R. China	
Contact	Haifeng Liu, Registration Manager ZheJiang Decans Medical Devices Co., Ltd. No.2836 Xincheng Avenue, Gaozhao Street, Xiuzhou District, Jiaxing City, Zhejiang Province, 314031,P.R. China Postcode: 314031 Email: hfliu@decansmd.com Phone:+86 15210058659	
Subject Device	Trade name	HERA Interlocking Intramedullary Nailing System
	Regulatory Class	II
	Regulation Number	21 CFR 888.3020
	Classification Name	Intramedullary fixation rod
	Product Codes	HSB
	Common name for product codes	Intramedullary fixation rod
Primary Predicate Device	Manufacturer	Double Medical Technology Inc.
	Trade name	Double Medical Femoral Nail System
	510(k)	K172830
	Regulatory Class	II
	Regulation Number	21CFR 888.3020, 21CFR888.3040
	Classification Name	Intramedullary fixation rod Smooth or threaded metallic bone fixation fastener
	Product Codes	HSB,HWC
Additional Predicate Device	Manufacturer	Smith & Nephew, Inc.
	Trade name	TriGen InterTAN
	510(k)	K040212
	Regulatory Class	II
	Regulation Number	21CFR 888.3030
	Classification Name	Single/multiple component metallic bone fixation appliances and accessories
	Product Codes	JDS
Additional Predicate Device	Manufacturer	Smith & Nephew, Inc.
	Trade name	TriGen Trochanteric Antegrade Nail
	510(k)	K040462
	Regulatory Class	II
	Regulation Number	21CFR 888.3020
	Classification Name	Intramedullary fixation rod
	Product Codes	HSB
Additional Predicate Device	Manufacturer	Xiamen Double Engine Medical Material Co., Ltd.
	Trade name	Double Engine Intramedullary Nail Systems

	510(k)	K131609
	Regulatory Class	II
	Regulation Number	21CFR 888.3020
	Classification Name	Intramedullary fixation rod
	Product Codes	HSB
Indications for use	**(1)Femoral Trochanteric Fixation Nail System** Femoral Trochanteric Fixation Nail System is intended use to: a) Pertrochanteric, intertrochanteric or Subtrochanteric fractures; b) Combination fractures of femur; c) Pathological fractures or reconstruction following tumor resection and grafting; d) Poor healing of fracture, including nonunions, malunions and bone lengthening or shortening; e) Other fracture, including simple severely comminuted, spiral, long oblique and segmental fractures of femur. **(2)Antegrade Femoral Reconstruction Nail System** Antegrade Femoral Reconstruction Nail System rencon mode is intended use to Femoral shaft and neck fracture, standard mode is intended use to Femoral shaft fracture. **(3)Tibial Nail system** Tibial nail system is intended to be implanted into the medullary canal of tibia for alignment, stabilization, fixation of fractures caused by trauma or disease.	
Device Description	This intramedullary fixation nailing system is used for stabilization of shaft fracture in Femur and Tibia. It is implanted into medullary cavity inside of the long bone (Femur and Tibia) with a fracture, and the fractured long bone (Femur and Tibia) is fixed to the nail by using the locking screw or/and lag screw at the proximal and distal parts of the fractured part. The nailing system consists of Femoral Trochanteric Fixation Nail System, Antegrade Femoral Reconstruction Nail System and Tibial Nail system. The HERA interlocking intramedullary nailing system is a fracture fixation system and includes non-sterile implants intramedullary nails,locking screws,lag screws and end caps in various diameter and sizes. All implants are made of titanium alloy (Ti6Al4V) as per ISO 5832-3.	
Materials	Titanium alloy(Ti6Al4V)	
Patient Contact	Bone and surrounding tissue	
Contact Duration	long-term use, >30 days	
Sterilization Method	The implants and surgical instruments are non-sterile provided, and validated manual cleaning and steam sterilization instructions are provided for the end user.The implants are single use only and the surgical instrument may be reused.	
Environment of Use	Healthcare facility/Hospital	
Single Use	Yes	
Summary of indication for use and technological characteristics	The HERA interlocking intramedullary nailing system is substantially equivalent to the predicate devices when evaluating indication for use and technological characteristics.The subject device has identical indication for use and technological characteristics as the predicate device.	
Non-clinical test	Performance bench testing	

	The following testing items were conducted for the subject device: ● Static and Dynamic bending test, IMFD torsional test per ASTM F1264-24. ● Axial pullout test, Insertion and removal test, Insertion test and Torsional test per ASTM F543-23. ● Static and Dynamic cantilever bending test per ASTM F384-24. ● Cutout test and Dynamic cutout test Cleaning and Sterilization The implant devices are provided non-sterile. Validated manual cleaning and steam sterilization instructions are provided for the end user before implantation. The recommended sterilization method was validated as per ISO 17665-1. Biocompatibility test The following biocompatibility tests were performed per ISO10993-1, and the test results demonstrate that the device meets biological safety requirements. • In vitro cytotoxicity Test per ISO 10993-5 • Skin sensitization Test per ISO 10993-10 • Intracutaneous Reactivity Test per ISO 10993-23 • Pyrogen Test per ISO 10993-11 • Chemical Characterization per ISO 10993-18 • Toxicological risk assessment of extractable chemicals per ISO 10993-17
Performance - Animal	No animal study data is submitted in this 510(k).
Performance - Clinical	No clinical study data is submitted in this 510(k).
Conclusion	The non-clinical data demonstrates the HERA interlocking intramedullary nailing system is substantially equivalent to the predicate device.