



February 27, 2026

Hankil Tech Medical Co., Ltd.  
Jeong-Yup Kim  
CEO  
452-29, Pureundeulpan-Ro, Paltan-Myeon  
Hwaseong-Si, 18532  
Republic of Korea

Re: K254249

Trade/Device Name: HKT Anatomical Locking Trauma System  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: Class II  
Product Code: HRS, HWC, HTN  
Dated: December 18, 2025  
Received: December 29, 2025

Dear Jeong-Yup Kim:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**CHRISTOPHER FERREIRA -S**

Christopher Ferreira, M.S.

Assistant Director

DHT6C: Division of Restorative,  
Repair, and Trauma 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.

K254249

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Please provide the device trade name(s).

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HKT Anatomical Locking Trauma System

Please provide your Indications for Use below.

?

The HKT Anatomical Locking Trauma System is intended for adult patients for fixation of fractures, osteotomies, and non-unions of the clavicle, humerus, elbow, radius, ulna, hand, tibia and foot.

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

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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## Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Hankil Tech Medical Co., Ltd
Applicant Address	452-29, Pureundeulpan-ro, Paltan-myeon Hwaseong-si 18532 Korea, Republic of
Applicant Contact Telephone	+82 31 354 6369
Applicant Contact	Mr. Jeong-Yup Kim
Applicant Contact Email	hankil@hankiltech.com

## Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	HKT Anatomical Locking Trauma System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS, HWC, HTN

## Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231213	HKT Anatomical Locking Trauma System	HRS

## Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The HKT Anatomical Locking Trauma System is a collection of implantable bone plates and bone screws. The HKT Anatomical Locking Trauma System is intended for adult patients for fixation of fractures, osteotomies, and non-unions of the clavicle, humerus, elbow, radius, ulna, hand, tibia and foot. This system consists of Bone Plates, Bone Screws and Washers

## Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The HKT Anatomical Locking Trauma System is intended for adult patients for fixation of fractures, osteotomies, and non-unions of the clavicle, humerus, elbow, radius, ulna, hand, tibia and foot.

## Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

Subject device HKT Anatomical Locking Trauma System and approved predicate devices for each intended anatomical location have the same intended use, similar indications, technical characteristics, and principles of operation. Despite minor differences in sizes of the device, the devices range in similar shapes and configurations. Additionally, mechanical testing on worst case subject devices was conducted and showed that the device performs as expected. All mechanical specifications and properties were considered according to applicable standards, and comparison to the mechanical properties of the predicate device demonstrated that both devices have equivalent mechanical performance. The similar indications for use, technological characteristics, and performance characteristics for the proposed HKT Anatomical Locking Trauma System are assessed to be substantially equivalent to the predicate devices.

## Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

Subject device HKT Anatomical Locking Trauma System and approved predicate devices for each intended anatomical location have the same intended use, similar indications, technical characteristics, and principles of operation. Despite minor differences in sizes of the device, the devices range in similar shapes and configurations. Additionally, mechanical testing on worst case subject devices was conducted and showed that the device performs as expected. All mechanical specifications and properties were considered according to applicable standards, and comparison to the mechanical properties of the predicate device demonstrated that both devices have equivalent mechanical performance. The similar indications for use, technological characteristics, and performance characteristics for the proposed HKT Anatomical Locking Trauma System are assessed to be substantially equivalent to the predicate devices.

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

The following tests were performed to demonstrate performance and safety based on current industry standards:

- Biocompatibility:

- o Cytotoxicity per ISO 10993-5
- o Sensitization per ISO 10993-10
- o Irritation per ISO 10993-10 and ISO 10993-23
- o Acute and Subacute/Subchronic Systemic Toxicity per ISO 10993-11
- o Material Mediated Pyrogenicity per ISO 10993-11
- o Genotoxicity per ISO 10993-3

- Performance Testing:

- o Standard Specification and Test Method for Metallic Bone Plates per ASTM F382
- o Standard Specification and Test Methods for Metallic Medical Bone Screws per ASTM F543

N/A

The results of these tests indicate that the HKT Anatomical Locking Trauma System is substantially equivalent to the predicate device.