January 19, 2024

Hankil Tech Medical Co., Ltd
% Kim Jeong-Yup
CEO
452-29, Pureundeulpan-ro, Paltan-myeon
Hwaseong-si, 18532
Korea, South

Re: K231213
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
Dated: December 21, 2023
Received: December 21, 2023

Dear Kim Jeong-Yup:

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.

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231213

Device Name

HKT Anatomical Locking Trauma System

Indications for Use *(Describe)*

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

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) Summary

DATE PREPARED
January 18, 2024

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	HKT Anatomical Locking Trauma System
Common Name:	Plate, Fixation, Bone and Screw, Fixation, Bone
Regulation Numbers:	21 CFR 888.3030, 21 CFR 888.3040
Classification Names:	Single/multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation fastener
Class:	II
Product Code:	HRS, HWC
Premarket Review:	OHT6/Orthopedic Devices (DHT6C)
Review Panel:	Orthopedic

PREDICATE DEVICE IDENTIFICATION
The HKT Anatomical Locking Trauma System is substantially equivalent to the following primary predicate:

510(k) Number	*Predicate Device Name / Manufacturer*
K000684	Small Fragment Dynamic Compression Locking (DCL) System/ Synthes (USA)

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION
The HKT Anatomical Locking Trauma System consists of metallic bone fixation plates and metallic screw fasteners. The bone plates and screws are composed of titanium alloy Ti-6Al-4V and commercially pure (Cp) titanium. The devices are used for fixation of fractures, osteotomies, and non-unions of the clavicle, tibia, femur, fibula, radius, ulna, humerus and pelvis. The bone plates are

anatomically pre-contoured and offered in various shapes and sizes to allow for the orthopedic surgeon or equivalent medical professional to choose which device best fits each patient within the indication for use.

INDICATIONS FOR USE

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

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Hankil Tech Medical believes that the HKT Anatomical Locking Trauma System is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design and dimensions and uses similar materials to the device cleared in K000684. Both the subject and predicate devices offer plate models to fit various anatomical locations. The subject device bone plates and screws are offered in additional sizes and shapes that are not necessarily identical to the predicate device configurations, but these differences do not affect the indications or intended use of the devices. The subject device has the same intended use and similar technological characteristics such that differences in the configurations and sizes of bone screws and bone plates do not raise different questions of safety and effectiveness compared to the devices cleared in K000684. These technological characteristics have undergone testing to ensure the device is substantially equivalent to the predicate.

SUMMARY OF NON-CLINICAL TESTING

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

- Biocompatibility:
  - Scientific Justification
  - Cytotoxicity per ISO 10993-5
  - Irritation per ISO 10993-23
  - Acute and Subacute/Subchronic Systemic Toxicity per ISO 10993-11

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

  For all implants except the iliac plate, test results were compared to FDA guidance documents, "*Orthopedic Fracture Fixation Plates - Performance Criteria for Safety and Performance Based Pathway*" and "*Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway*."

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

SUMMARY OF NON-CLINICAL TESTING
No clinical data was provided to demonstrate substantial equivalence.

CONCLUSION
Based on the testing performed, including biocompatibility and performance testing per recognized consensus standards, it can be concluded that the subject devices are substantially equivalent to the predicate devices. 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.