April 24, 2025

Canwell Medical Co., Ltd.
% Jiangfeng Ren
Regulatory Affairs
Shanghai Ling Fu Technology Co., Ltd.
Room 1115, Block A, Xuhui Vanke Centre, No. 55 Ding'an Road,
Xuhui District
Shanghai, Shanghai 200030
China

Re: K242973
Trade/Device Name: CanMINI Hand and Foot 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: September 15, 2024
Received: September 26, 2024

Dear Jiangfeng Ren:

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.

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,

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

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.

510(k) Number *(if known)*
K242973

Device Name
CanMINI Hand and Foot System

Indications for Use *(Describe)*
The CanMINI Hand and Foot System is indicated for fixation of small bones and small bone fragments in the hand and foot. The devices are intended to be single-use and sterilized before use.

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.

K242973
510(k) Summary

I. Submitter

CANWELL MEDICAL CO., LTD.

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Contact Person

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II. Correspondent

Company	Shanghai Ling Fu Technology Co., Ltd. Room 1115, Block A, Xuhui Vanke Centre, No. 55 Ding'an Road, Xuhui District, Shanghai, P.R.China
Contact person:	Jiangfeng REN Regulatory affairs Phone: 86-21-33561520 Email: jiangfeng.ren@llins-tech.com

III. Proposed Device

Trade Name of Device:	CanMINI Hand and Foot System
Common Name:	Plate, Fixation, Bone; Screw, Fixation, Bone
Regulation Number:	21 CFR 888.3030 (primary), 21 CFR 888.3040
Regulatory Class:	Class II
Product code:	HRS (primary), HWC
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories; Smooth or threaded metallic bone fixation fastener
Review Panel:	Orthopedic

IV. Predicate Devices

IV.1. Primary Predicate Device

Trade name:	Synthes (USA) 1.5mm Mini Fragment LCP System
Common name:	/
Classification:	Class II, 21 CFR 888.3030
Product Code:	HRS
Premarket Notification:	K090047
Manufacturer:	Synthes (USA)

IV.2. Additional Predicate Devices

Trade name:	Double Engine Bone Plate And Screw Systems
Common name:	/

Classification:	Class II, 21 CFR 888.3030
Product Code:	HRS, HWC
Premarket Notification:	K130108
Manufacturer:	XIAMEN DOUBLE ENGINE MEDICAL MATERIAL CO., LTD

Trade name:	Single/multiple Component Metallic Bone Fixation Appliances and Accessories
Common name:	Plate, Fixation, Bone
Classification:	Class II, 21 CFR 888.3030
Product Code:	HRS
Premarket Notification:	K033639
Manufacturer:	Acumed LLC

Trade name:	Synthes (USA) Modular Mini Fragment LCP System
Common name:	/
Classification:	Class II, 21 CFR 888.3030
Product Code:	HRS
Premarket Notification:	K063049
Manufacturer:	Synthes (USA)

Trade name:	PERI-LOC Periarticular Locked Plating System
Common name:	Bone Plates and Bone Screws
Classification:	Class II, 21 CFR 888.3030
Product Code:	HRS
Premarket Notification:	K092015
Manufacturer:	Smith & Nephew, Inc.

Trade name:	Arthrex Mini Comprehensive Fixation System - 2.0mm & 2.4mm Module
Common name:	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Classification:	Class II, 21 CFR 888.3030, 21 CFR 888.3040
Product Code:	HRS; HWC
Premarket Notification:	K191344
Manufacturer:	Arthrex Inc.

Trade name:	ACUTRACT

Common name:	/
Classification:	Class II, 21 CFR 888.3040
Product Code:	HWC
Premarket Notification:	K930834
Manufacturer:	ACUMED, INC.

Trade name:	Synthes (USA) / 3.5 nun and 4.5 nun Locking Compression Plate (LCP) System with Expanded Indications
Common name:	/
Premarket Notification:	Class II, 21 CFR 888.3030
Product Code:	HRS; HWC
Premarket Notification:	K082807
Manufacturer:	Synthes (USA)

V. Device Description Summary

The CanMINI Hand and Foot System, manufactured by CANWELL MEDICAL CO. LTD., is an orthopedic fixation system designed to stabilize fractures or osteotomies of the small bones in the hand and foot. The system includes a variety of bone plates and screws made from high-quality titanium and titanium alloy, ensuring both strength and biocompatibility. The primary materials used in the CanMINI Hand and Foot System are pure titanium, conforming to ASTM F67 standards, and titanium alloy, conforming to ASTM F1472 standards.

The CanMINI Hand and Foot System consists of multiple components, each designed to address specific clinical needs in orthopedic surgery. The key components are bone plates and bone screws. The bone plates include straight type bone plates such as models FZSQ01Ⅰ, FZSQ12, FZSQ38, FZSQ39Ⅰ, FZSQ39Ⅱ, FZSQ39Ⅲ, FZSQ40Ⅰ, and FZSQ40Ⅱ, as well as supporting type non-locking bone plates like models FBC54Ⅰ, FBC54Ⅱ, FBC55, FBC56, and FBC58. Additionally, the system features supporting type locking bone plates including models FBCS29, FBCS57Ⅰ, FBCS57Ⅱ, FBCS59, FBCS60, FBCS86, FBCS87, FBCS88, FBCS89, FBCS96Ⅰ, FBCS96Ⅱ, FBCS99Ⅰ, FBCS99Ⅱ, FBCS132, FBCS134, and FBCS135. The bone screws are also categorized into different types, including metal non-locking bone screws with models FHAQ02 Ⅰ, FHAQ03 Ⅰ, FHAQ06 Ⅰ, metal locking screws with models FHAS04 Ⅰ, FHCS04 Ⅰ, and cannulated screws with model FGJYD Ⅹ. The bone plates and screws in the CanMINI Hand and Foot System come in a range of sizes to accommodate different anatomical and clinical requirements. For example, the 6-hole 1.5mm phalangeal metacarpal locking plate has dimensions of 29.7 mm in length, 4.7 mm in width, and 0.95 mm in thickness, while the 8-hole 2.4mm condylar locking plate has dimensions of 59.0 mm in length, 6.5 mm in width, and 1.4 mm in thickness.

The CanMINI Hand and Foot System is intended for the stabilization of fractures and

osteotomies in the small bones of the hand and foot. It provides mechanical support to the bone during the healing process by maintaining proper alignment and stabilizing the fracture site. The system is designed to be used by orthopedic surgeons in various clinical scenarios involving bone fractures, including but not limited to, calcaneal fractures, fracture displacements, and non-union fractures. The clinical benefits of the system include providing critical stabilization and support during the healing of orthopedic fractures. This system aids in the proper alignment of fractured bones, enhances the healing process, and reduces the likelihood of complications such as malunion or delayed union.

The CanMINI Hand and Foot System is supplied in a non-sterile state and must be sterilized before use. It is intended for single use only.

Table 1 List of product types and specifications

Model	**Product Description**	**Specifications**
FZSQ38	1.5mm Phalangeal Metacarpal Locking Plate	6-12 holes
FZSQ39Ⅰ	1.5mm Locking Plate	4-10 holes
FBCS86	1.5mm Mini Locking Plate（T-Shape）	4-8 holes
FBCS87	1.5mm Locking Support Plate	8 holes; R, L
FBCS88	1.5mm Mini Locking Plate(Y-shape)	4-8 holes
FBCS89	1.5mm Mini Condylar Locking Plate	4-8 holes
FZSQ01Ⅰ	2.0mm Tubular Plate	2-7 holes
FZSQ40Ⅰ	2.0mm Adaption Locking Plate	12 holes
FBCS57Ⅰ	2.0mm Condylar Locking Plate	3-7 holes
FBCS96Ⅰ	2.0mm Locking Y-Plate	4-7 holes
FBCS99Ⅰ	2.0mm Locking T-Plate	4-7 holes
FBC54Ⅱ	2.0mm T-Plate	2-5 holes
FBC55	2.0mm L-Plate	4, 5 holes; R, L
FBC56	2.0mm L-Plate, Oblique-angled	4, 5 holes; R, L
FBC58	2.0mm T-Plate(head 3 holes)	4-8 holes
FZSQ39Ⅱ	2.0mm Locking Plate	4-10 holes
FZSQ12	2.4mm Reconstruction Plate	4-6 holes
FZSQ39ⅢⅠ	2.4mm Locking Plate	4-10 holes
FZSQ40Ⅱ	2.4mm Adaption Locking Plate	12 holes
FBCS57Ⅱ	2.4mm Condylar Locking Plate	3-7 holes
FBC54Ⅰ	2.4mm T-Plate	2-5 holes
FBCS96Ⅱ	2.4mm Mini Locking Plate(Y-shape)	4-7 holes
FBCS99Ⅱ	2.4mm Mini Locking Plate(T-shape)	4-7 holes
FBCS59	Posterior Tuberosity Calcaneal Locking Plate	3, 4; R, L
FBCS60	Anterior Process Calcaneal Locking Plate	3, 4; R, L
FBCS132	Calcaneal Locking Plate I	Small, Medium, Large; R, L
FBCS29	Calcaneal Locking Plate II	15 holes; 69mm,76 mm; R, L
FBCS134	Calcaneal Locking Plate III	Small, Medium, Large; R, L
FBCS135	Calcaneal Locking Plate IV	53mm-68 mm; R, L
FHAS04Ⅰ	Locking screw, Self-Tapping	Φ1.5, 6~20 mm
		Φ2.0, 6~30 mm
FHCS04Ⅰ	Locking screw, Self-Tapping	Φ2.4, 6~30 mm
		Φ3.5, 10~55 mm
FHAQ02Ⅰ	Cortex Screw (Phillips), Self-Tapping	Φ2.0, 6~38 mm
		Φ2.4, 6~40 mm

FHAQ06Ⅰ	Cortex Screw, Self-Tapping	Φ1.5, 6~20 mm
		Φ2.0, 6~38 mm
		Φ2.4, 6~40 mm
FHAQ03Ⅰ	Cortex Screw, Self-Tapping	Φ3.5, 12~60 mm
FGJYDX	Headless Compression Screw	Φ2.5, 8~30 mm
		Φ3.0, 10~50 mm
		Φ3.5, 16~50 mm
		Φ4.0, 16~60 mm
		Φ4.5, 20~60 mm
		Φ5.0, 25~80 mm
		Φ6.5, 40~120 mm

VI. Indications for use

The CanMINI Hand and Foot System is indicated for fixation of small bones and small bone fragments in the hand and foot. The devices are intended to be single-use and sterilized before use.

VII. Comparison of technological characteristics with the predicate devices

VII.1. Indications for Use Comparison

Both the subject device and the predicate devices are intended for the stabilization of fractured or surgically cut bones, providing structural support as the bone heals. The differences in the exact wording of the indications for use do not introduce any deviations in clinical application or safety profile. The intended use remains consistent across all devices, ensuring that the subject device is suitable for its designed purpose, in full alignment with the predicates.

VII.2. Technological Comparison

The subject device meets the FDA's Safety and Performance Based Pathway by adhering to ASTM standards (F67 and F1472 for materials, F382 and F543 for mechanical performance) and demonstrates substantial equivalence to the predicate devices. The minor differences between the subject and predicate devices, such as different dimensions, variations in hole numbers and specific materials, do not raise new questions of safety or effectiveness. Importantly, since the subject device complies with the FDA-identified performance criteria, no further direct SE comparison is necessary.

VIII. Non-Clinical Testing

Key tests include:

1. Axial Pullout Strength (per ASTM F543-23): This test evaluates the axial extraction strength of the screws, confirming that the device meets the minimum performance criteria for bone screws.

2. Single Cycle Bend Testing (per ASTM F382-24): This test assesses the bending strength and stiffness of the 2.4mm locking plates.

3. Driving Torque and Torsional Properties (per ASTM F543-23): Evaluations were conducted on metallic bone screws and locking screws to ensure they meet the required torsional strength and torque limits.

In addition to the mechanical performance tests, the nonclinical evaluation of the CanMINI Hand and Foot System also included material characterization tests to ensure compliance with ASTM material

standards. The materials used in the device, Pure Titanium (Grade 3) and Titanium Alloy Ti6Al4V, were evaluated in accordance with the following standards:

- Material Composition (per ASTM F67-13 for unalloyed titanium and ASTM F1472-23 for titanium alloy): These tests ensure that the chemical composition of the materials complies with established limits for elements such as nitrogen, carbon, and oxygen. The materials are certified to meet the requirements for surgical implants.

IX. Clinical Testing

Not Applicable.

X. Conclusion

The subject device meets the FDA's Safety and Performance Based Pathway by adhering to ASTM standards (F67 and F1472 for materials, F382 and F543 for mechanical performance) Therefore, it can be concluded that the subject device as safe and effective as the predicate devices.