

K242973 CanMINI Hand and Foot SystemApr 24, 2025
210 days to decisionK242973 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k242973/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 26, 2024
Decision date	Apr 24, 2025
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Canwell Medical Co., Ltd.
Location	Jinhua, CN
Contact	Hui Chen
510(k) history	3 submissions · 3 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	Shanghai Lingfu Technology Co., Ltd.
Contact	Jiangfeng Ren

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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