

K231213 HKT Anatomical Locking Trauma SystemJan 19, 2024
266 days to decisionK231213 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k231213/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 28, 2023
Decision date	Jan 19, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hankil Tech Medical Co., Ltd.
Location	Hwaseong-Si, KR
Contact	Kim Jeong-Yup
Website	https://www.hankiltech.co.kr
510(k) history	2 submissions · 2 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Lucie Dalet

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231213/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026