FDA 510(k) Premarket Notification

K231213 HKT Anatomical Locking Trauma System

CLEARED

Jan 19, 2024
266 days to decision

K231213 · 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