

K241128 TDM Plate and Screw SystemDec 5, 2024
225 days to decisionK241128 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k241128/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 24, 2024
Decision date	Dec 5, 2024
Days to decision	225 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tdm Co., Ltd.
Location	Gwangju, KR
Contact	Jungwook Choi
510(k) history	11 submissions · 11 cleared · 2018-2024

REGULATORY CONSULTANT

Consulting firm	Eerkie Corporation
Contact	Jeena Mathai

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/k241128/> 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 14, 2026