

K232115 TDM Large Bone Plate and Screw SystemApr 5, 2024
266 days to decisionK232115 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k232115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jul 14, 2023
Decision date	Apr 5, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Mtech Group, LLC
Contact	Dave Kim

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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