

**K231860 TDM Screw System**Jan 18, 2024  
209 days to decisionK231860 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k231860/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 23, 2023
Decision date	Jan 18, 2024
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tdm Co., Ltd.</b>
Location	Gwangju, KR
Contact	Jung Wook Choi
510(k) history	11 submissions · 11 cleared · 2018-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Eerkie Corporation</b>
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)

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