

**K190830 TDM Screw Systems**Sep 13, 2019  
165 days to decisionK190830 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k190830/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Apr 1, 2019
Decision date	Sep 13, 2019
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190830/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026