

**K230071 Femur Reconstruction Interlocking Nail System,  
Femur Retrograde Interlocking Nail System, Humerus  
Interlocking Nail System, Tibia Interlocking Nail System,  
Compression Hip Nail System**Aug 22, 2024  
590 days to decisionK230071 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k230071/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Jan 10, 2023
Decision date	Aug 22, 2024
Days to decision	590 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>Mtechgroup</b>
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)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230071/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026