

**K221221 Advanced Intramedullary Nail System**Dec 21, 2022  
238 days to decisionK221221 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k221221/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Apr 27, 2022
Decision date	Dec 21, 2022
Days to decision	238 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Double Medical Technology, Inc.</b>
Location	Xiamen, CN
Contact	Yan Zuo
510(k) history	12 submissions · 12 cleared · 2016-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221221/> 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 26, 2026