

**K221621 Pro-X1™ Trochanteric Nailing System**Mar 6, 2023  
276 days to decisionK221621 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k221621/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Jun 3, 2022
Decision date	Mar 6, 2023
Days to decision	276 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>X-Bolt Orthopedics</b>
Location	Santry, IE
Contact	Brian Thornes
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mcra, LLC</b>
Contact	Hollace Saas Rhodes

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](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221621/> 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 27, 2026