

**K181640 X-BOLT Hip Fracture Fixation System**Oct 12, 2018  
113 days to decisionK181640 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k181640/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Jun 21, 2018
Decision date	Oct 12, 2018
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>X-Bolt Orthopaedics</b>
Location	Dublin, IE
Contact	Brian Thornes
510(k) history	1 submissions · 1 cleared · 2018-2018

**REGULATORY CONSULTANT**

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Consulting firm	<b>Musculoskeletal Clinical Regulatory Advisers, LLC</b>
Contact	Brian Thornes

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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