

**K203228 DART-FIRE EDGE Cannulated Screw System**May 11, 2021  
190 days to decisionK203228 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k203228/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Nov 2, 2020
Decision date	May 11, 2021
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wright Medical</b>
Location	Memphis, TN, US
Contact	Michael Mullins
510(k) history	3 submissions · 3 cleared · 2017-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203228/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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