

**K201259 ORTHOLOC 2 with 3Di Technology Pilon Fracture  
Plating System**Jan 8, 2021  
242 days to decisionK201259 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k201259/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	May 11, 2020
Decision date	Jan 8, 2021
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wrightmedicaltechnologyinc</b>
Location	Arlington, TN, US
Contact	Anna Hinton
510(k) history	302 submissions · 291 cleared · 1993-2023

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201259/> 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 13, 2026