

**K182810 Distal Radius Plating System**Dec 10, 2018  
68 days to decisionK182810 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k182810/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Oct 3, 2018
Decision date	Dec 10, 2018
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Miami Device Solutions, LLC</b>
Location	Miami, FL, US
Contact	Michelle Montesino
510(k) history	6 submissions · 6 cleared · 2016-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182810/> 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 June 28, 2026