

**K211518 2.4mm X 130cm Phoenix Deflecting Atherectomy System, 1.5mm X 149cm Phoenix Atherectomy System**Jun 14, 2021  
28 days to decisionK211518 · Product code: **MCW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k211518/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	May 17, 2021
Decision date	Jun 14, 2021
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Volcano Atheromed, Inc.</b>
Location	Menlo Park, CA, US
Contact	Jean Chang
510(k) history	7 submissions · 7 cleared · 2014-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211518/> 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 27, 2026