

**K202835 Auryon Atherectomy System**Dec 2, 2020  
68 days to decisionK202835 · Product code: **MCW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k202835/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Sep 25, 2020
Decision date	Dec 2, 2020
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Eximo Medical, Ltd.</b>
Location	Rehovot, IL
Contact	Yoel Zabar
510(k) history	7 submissions · 7 cleared · 2018-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202835/> 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 26, 2026