

**K220116 Auryon Atherectomy Catheters**Sep 26, 2022  
255 days to decisionK220116 · Product code: **MCW** · CardiovascularSource: <https://www.510kdatabase.net/k220116/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Jan 14, 2022
Decision date	Sep 26, 2022
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Angiodynamics</b>
Contact	James Welsh

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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