

K230709 Auryon Atherectomy SystemJun 9, 2023
87 days to decisionK230709 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k230709/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Mar 14, 2023
Decision date	Jun 9, 2023
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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