

K233668 Auryon Atherectomy Catheter 1.5 mm XL, Hydrophilic Coating (EXM-4010-H000), Auryon Atherectomy Catheter 0.9 mm XL, Hydrophilic Coating (EXM-4011-H000), Auryon Atherectomy Catheter 1.5 mm XL (EXM -4010-0000), Auryon Atherectomy Catheter 0.9 mm XL (EXM-4011-0000)

Dec 15, 2023
30 days to decision

K233668 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k233668/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Nov 15, 2023
Decision date	Dec 15, 2023
Days to decision	30 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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Device record: <https://www.510kdatabase.net/k233668/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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