

K210801 AXINON® LDL-p Test SystemJul 19, 2023
854 days to decisionK210801 · Product code: **MRR** · Chemistry
Source: <https://www.510kdatabase.net/k210801/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Low Density, Lipoprotein (MRR)
Date received	Mar 17, 2021
Decision date	Jul 19, 2023
Days to decision	854 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Numares AG
Location	Regensburg, DE
Contact	Stefanie Dukorn
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210801/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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