

**K233216 CLEWICU System**Jan 13, 2024  
107 days to decisionK233216 · Product code: **QNL** · Cardiovascular  
Source: <https://www.510kdatabase.net/k233216/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medium-term Adjunctive Predictive Cardiovascular Indicator (QNL)
Date received	Sep 28, 2023
Decision date	Jan 13, 2024
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Clew Medical , Ltd.</b>
Location	Netanya, IL
Contact	Avidgor Faians
510(k) history	2 submissions · 2 cleared · 2021-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233216/> 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 13, 2026