

**K200717 CLEWICU System (ClewICU Server and ClewICU Unit)**Jan 9, 2021  
297 days to decisionK200717 · Product code: **QNL** · Cardiovascular  
Source: <https://www.510kdatabase.net/k200717/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medium-term Adjunctive Predictive Cardiovascular Indicator (QNL)
Date received	Mar 18, 2020
Decision date	Jan 9, 2021
Days to decision	297 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Manatt, Phelps, &amp; Phillips, LLP</b>
Contact	Yarmela Pavlovic

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200717/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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