K200717 CLEWICU System (ClewICUServer and ClewICUnitor)

CLEARED

Jan 9, 2021
297 days to decision

K200717 · Product code: **QNL** · Cardiovascular
Source: https://www.510kdatabase.net/k200717/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Manatt, Phelps, & Phillips, Llp**
Contact	Yarmela Pavlovic

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