

K232107 °M Warmer SystemMay 31, 2024
322 days to decisionK232107 · Product code: **LGZ** · General HospitalSource: <https://www.510kdatabase.net/k232107/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Warmer, Thermal, Infusion Fluid (LGZ)
Date received	Jul 14, 2023
Decision date	May 31, 2024
Days to decision	322 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mequ A/S
Location	Kobenhavn N, DK
Contact	Ulrik Andersen
510(k) history	2 submissions · 2 cleared · 2024-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232107/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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