

K243437 mOm Essential Incubator (ME1)Aug 14, 2025
282 days to decisionK243437 · Product code: **FMZ** · General Hospital
Source: <https://www.510kdatabase.net/k243437/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Nov 5, 2024
Decision date	Aug 14, 2025
Days to decision	282 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mom Incubators Limited
Location	Nottingham, GB
Contact	Rosalyn Archer
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243437/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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