

K251619 Babyleo TN500Feb 13, 2026
262 days to decisionK251619 · Product code: **FMZ** · General Hospital
Source: <https://www.510kdatabase.net/k251619/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	May 27, 2025
Decision date	Feb 13, 2026
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dr?gerwerk AG & Co KGaA
Location	Luebeck, DE
Contact	Lyubov Lange
510(k) history	4 submissions · 4 cleared · 2022-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251619/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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