

**K162821 Babyleo TN500**Jun 23, 2017  
259 days to decisionK162821 · Product code: **FMZ** · General Hospital  
Source: <https://www.510kdatabase.net/k162821/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Oct 7, 2016
Decision date	Jun 23, 2017
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Draegerwerk AG &amp; CO KgaA</b>
Location	L?beck, DE
Contact	Bettina Moebius
510(k) history	7 submissions · 7 cleared · 2010-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162821/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026