

**K182859 Babyleo TN500**Feb 22, 2019  
134 days to decisionK182859 · Product code: **FMZ** · General Hospital  
Source: <https://www.510kdatabase.net/k182859/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Incubator, Neonatal (FMZ)
Date received	Oct 11, 2018
Decision date	Feb 22, 2019
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dragerwerk AG &amp; CO Kгаа</b>
Location	L?beck, DE
Contact	Dr. Bettina Mobius
510(k) history	2 submissions · 2 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Draeger Medical Sytems, Inc.</b>
Contact	Gale Winarsky

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

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