

**K230278 Babyroo TN300**May 30, 2023  
118 days to decisionK230278 · Product code: **FMT** · General HospitalSource: <https://www.510kdatabase.net/k230278/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Warmer, Infant Radiant (FMT)
Date received	Feb 1, 2023
Decision date	May 30, 2023
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Draeger Medical Systems, Inc.</b>
Location	Danvers, MA, US
Contact	Karl Nittinger
510(k) history	48 submissions · 48 cleared · 2003-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230278/> 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 14, 2026