

**K243606 Babyroo TN300**Jan 17, 2025  
57 days to decisionK243606 · Product code: **FMT** · General Hospital  
Source: <https://www.510kdatabase.net/k243606/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Warmer, Infant Radiant (FMT)
Date received	Nov 21, 2024
Decision date	Jan 17, 2025
Days to decision	57 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/k243606/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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