

**K053399 VERSALET 7700 CARE CENTER**Aug 4, 2006  
241 days to decisionK053399 · Product code: **FMZ** · General Hospital  
Source: <https://www.510kdatabase.net/k053399/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Dec 6, 2005
Decision date	Aug 4, 2006
Days to decision	241 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Draeger Medical Infant Care, Inc.</b>
Location	Hatboro, PA, US
Contact	MONICA FERRANTE
510(k) history	2 submissions · 2 cleared · 2005-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053399/> 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 June 30, 2026