

**K040068 BILIBLANKET PLUS HIGH OUTPUT PHOTOTHERAPY SYSTEM**Apr 16, 2004  
93 days to decisionK040068 · Product code: **FMZ** · General Hospital  
Source: <https://www.510kdatabase.net/k040068/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Jan 14, 2004
Decision date	Apr 16, 2004
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ohmeda Medical</b>
Location	Madison, WI, US
Contact	ALBERTO F PROFUMO
510(k) history	120 submissions · 118 cleared · 1984-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040068/>; 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