

**K945467 BABYTHERM 8000 WB**Apr 28, 1995  
172 days to decisionK945467 · Product code: **ILO** · Physical Medicine  
Source: <https://www.510kdatabase.net/k945467/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pack, Hot Or Cold, Water Circulating (ILO)
Date received	Nov 7, 1994
Decision date	Apr 28, 1995
Days to decision	172 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Drager, Inc.</b>
Location	Pittsburgh, PA, US
Contact	HARALD KNEUER
510(k) history	20 submissions · 15 cleared · 1991-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945467/> 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 25, 2026