

**K954716 DEROYAL INDUSTRIES INFANT HEEL WARMER**Jan 11, 1996  
90 days to decisionK954716 · Product code: **MPO** · Physical MedicineSource: <https://www.510kdatabase.net/k954716/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Infant Heel Warmer (chemical Heat Pack) (MPO)
Date received	Oct 13, 1995
Decision date	Jan 11, 1996
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Debusk Knitting Mills, Div. Deroyal Industries</b>
Location	Knoxville, TN, US
Contact	DEBRA F MANNING
510(k) history	4 submissions · 4 cleared · 1996-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954716/> 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 29, 2026