

**K151845 Infant Heel Warmer (Model 24401) and WarmGel Infant Heel Warmer (Model 20418)**Mar 18, 2016  
255 days to decisionK151845 · Product code: **MPO** · Physical MedicineSource: <https://www.510kdatabase.net/k151845/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Infant Heel Warmer (chemical Heat Pack) (MPO)
Date received	Jul 7, 2015
Decision date	Mar 18, 2016
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>CooperSurgical, Inc.</b>
Location	Mountain View, CA, US
Contact	ROAIDA JOHNSON
510(k) history	41 submissions · 40 cleared · 1991-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151845/> 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