

K103549 DENOVO TEDDY GEL INFANT HEEL WARMERApr 8, 2011
126 days to decisionK103549 · Product code: **MPO** · Physical MedicineSource: <https://www.510kdatabase.net/k103549/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Infant Heel Warmer (chemical Heat Pack) (MPO)
Date received	Dec 3, 2010
Decision date	Apr 8, 2011
Days to decision	126 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Denovo Products, LLC
Location	Fort Myers, FL, US
Contact	DALE WALTERS
510(k) history	1 submissions · 1 cleared · 2011-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103549/> Data sourced from FDA 510(k) public records (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. - Generated June 19, 2026