

K221154 Infant Heel Warmer™Oct 7, 2022
169 days to decisionK221154 · Product code: **MPO** · Physical Medicine
Source: <https://www.510kdatabase.net/k221154/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Infant Heel Warmer (chemical Heat Pack) (MPO)
Date received	Apr 21, 2022
Decision date	Oct 7, 2022
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Heel Snuggler®

APPLICANT

Company	International Biomedical
Location	Austin, TX, US
Contact	Amy Pieper
510(k) history	8 submissions · 8 cleared · 2014-2022

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