

K221653 InfaTherm Disposable Infant Warming MattressOct 6, 2022
121 days to decisionK221653 · Product code: **IMD** · Physical Medicine
Source: <https://www.510kdatabase.net/k221653/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pack, Hot Or Cold, Disposable (IMD)
Date received	Jun 7, 2022
Decision date	Oct 6, 2022
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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