

K232627 HotDog Warming Mattress + Return ElectrodeApr 18, 2024
233 days to decisionK232627 · Product code: **DWJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k232627/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Thermal Regulating (DWJ)
Date received	Aug 29, 2023
Decision date	Apr 18, 2024
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Augustine Temperature Management, LLC
Location	Minneapolis, MN, US
Contact	Garrett Augustine
510(k) history	3 submissions · 3 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	Augustine Temperature Management
Contact	Garrett Augustine

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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