

K232508 Barrier EasyWarm Active Self-Warming BlanketSep 15, 2023
28 days to decisionK232508 · Product code: **DWJ** · CardiovascularSource: <https://www.510kdatabase.net/k232508/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Thermal Regulating (DWJ)
Date received	Aug 18, 2023
Decision date	Sep 15, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Molnlycke Health Care Us, LLC
Location	Norcross, GA, US
Contact	Megan Bevill
510(k) history	27 submissions · 27 cleared · 2006-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232508/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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