

**K132048 BARRIER EASYWARM ACTIVE SELF-WARMING
BLANKET**Nov 6, 2013
127 days to decisionK132048 · Product code: **DWJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k132048/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Jul 2, 2013
Decision date	Nov 6, 2013
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132048/> 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 2, 2026