

K260903 Hot Pink Pad Warming SystemApr 16, 2026
29 days to decisionK260903 · Product code: **DWJ** · CardiovascularSource: <https://www.510kdatabase.net/k260903/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Mar 18, 2026
Decision date	Apr 16, 2026
Days to decision	29 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xodus Medical, Inc.
Location	New Kensington, PA, US
Contact	Paul Lloyd
510(k) history	6 submissions · 6 cleared · 2006-2026

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260903/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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