

**K250979 Thermogard HQ™ Temperature Management System,
Thermogard XP® Temperature Management System
(VitalTemp™ Universal Pad)**Oct 15, 2025
198 days to decisionK250979 · Product code: **NZE** · Cardiovascular
Source: <https://www.510kdatabase.net/k250979/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hyperthermia Monitor (NZE)
Date received	Mar 31, 2025
Decision date	Oct 15, 2025
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zoll Circulation, Inc.
Location	San Jose, CA, US
Contact	Riki Chaudhary
510(k) history	8 submissions · 3 cleared · 2015-2025

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