

K240933 CarbonCool® SystemMar 18, 2025
347 days to decisionK240933 · Product code: **NZE** · Cardiovascular
Source: <https://www.510kdatabase.net/k240933/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hyperthermia Monitor (NZE)
Date received	Apr 5, 2024
Decision date	Mar 18, 2025
Days to decision	347 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Global Healthcare SG Sdn. Bhd
Location	Negeri Sembilan, MY
Contact	Keng Liang Cheng
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240933/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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