

K250401 AION TempShield™Mar 14, 2025
30 days to decisionK250401 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k250401/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Feb 12, 2025
Decision date	Mar 14, 2025
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aion Biosystems, Inc.
Location	Darien, CT, US
Contact	Samara Barend
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

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

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