FDA 510(k) Premarket Notification

K232010 iTEMPSHIELD

CLEARED

Aug 4, 2023
29 days to decision

K232010 · Product code: **FLL** · General Hospital
Source: https://www.510kdatabase.net/k232010/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Jul 6, 2023
Decision date	Aug 4, 2023
Days to decision	29 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aion Biosystems, Inc.**
Location	Darien, CT, US
Contact	Joseph Azary
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