FDA 510(k) Premarket Notification

K230298 Celsi Monitor

CLEARED

Aug 16, 2023
195 days to decision

K230298 · Product code: **FLL** · General Hospital
Source: https://www.510kdatabase.net/k230298/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Feb 2, 2023
Decision date	Aug 16, 2023
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hadleigh Health Technologies**
Location	San Rafael, CA, US
Contact	Molly McCabe
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Allison Komiyama

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