

**K230298 Celsi Monitor**Aug 16, 2023  
195 days to decisionK230298 · Product code: **FLL** · General Hospital  
Source: <https://www.510kdatabase.net/k230298/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>RQM+</b>
Contact	Allison Komiyama

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230298/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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