

K243778 Body Temperature Software (BTS)Feb 13, 2025
66 days to decisionK243778 · Product code: **QZA** · General Hospital
Source: <https://www.510kdatabase.net/k243778/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Body Temperature Sensing Software (QZA)
Date received	Dec 9, 2024
Decision date	Feb 13, 2025
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fitbit, LLC
Location	San Francisco, CA, US
Contact	Nathan Austin
510(k) history	2 submissions · 1 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243778/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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