

K250470 Ear Thermometer (EAR-E101)Jun 23, 2025
125 days to decisionK250470 · Product code: **FLL** · General HospitalSource: <https://www.510kdatabase.net/k250470/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Feb 18, 2025
Decision date	Jun 23, 2025
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Ear Thermometer (EAR-E102); Ear Thermometer (EAR-E103)

APPLICANT

Company	Shenzhen AOJ Medical Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Jack Wang
510(k) history	17 submissions · 17 cleared · 2018-2026

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