

K250878 YUWELL® Infrared Ear Thermometer (YHT100)May 22, 2025
59 days to decisionK250878 · Product code: **FLL** · General HospitalSource: <https://www.510kdatabase.net/k250878/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Mar 24, 2025
Decision date	May 22, 2025
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	YUWELL® Infrared Ear Thermometer (YHT107)

APPLICANT

Company	Jiangsu Yuyue Medical Equipment& Supply Co., Ltd.
Location	Zhenjiang, CN
Contact	Fang (Fawn) Zhang
510(k) history	14 submissions · 14 cleared · 2009-2026

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