

K243136 Non-contact Forehead Infrared Thermometer (FC-IR2000, FC-IR205, FC-IR202, FC-IR206, FC-IR207, FC-IR209)Feb 14, 2025
137 days to decisionK243136 · Product code: FLL · General Hospital
Source: <https://www.510kdatabase.net/k243136/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Sep 30, 2024
Decision date	Feb 14, 2025
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Finicare Co., Ltd.
Location	Shenzhen, CN
Contact	Li Chao
510(k) history	6 submissions · 6 cleared · 2019-2025

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

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

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