

K243082 Infrared ThermometerApr 25, 2025
207 days to decisionK243082 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k243082/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Sep 30, 2024
Decision date	Apr 25, 2025
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Daxin Health Technology Co., Ltd.
Location	Guangzhou, CN
Contact	LuPeng Guo
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Share Info (Guangzhou) Medical Consultant , Ltd.
Contact	Cassie Lee

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243082/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026