

K220084 Infrared Forehead ThermometerSep 12, 2022
245 days to decisionK220084 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k220084/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Jan 10, 2022
Decision date	Sep 12, 2022
Days to decision	245 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Qingdao Yasee Medical Device Co., Ltd.
Location	Qingdao, CN
Contact	Shaoju Tian
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

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