

K201536 Infrared Forehead ThermometerFeb 10, 2021
247 days to decisionK201536 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k201536/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Jun 8, 2020
Decision date	Feb 10, 2021
Days to decision	247 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hangzhou Qingyuan Medical Equipment Technology Co., Ltd.
Location	Hangzhou, CN
Contact	Jenny Li
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Yoyo Chen

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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