

K221800 Infrared Thermometer (Model: Y20001, Y20002)Dec 14, 2022
176 days to decisionK221800 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k221800/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Jun 21, 2022
Decision date	Dec 14, 2022
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhangzhou Easepal Medical Science and Technology Co., Ltd.
Location	Zhangzhou, CN
Contact	Flower Flower
510(k) history	3 submissions · 3 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	Guangdong Jianda Medical Technology Co., Ltd.
Contact	Jet Li

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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