

K221211 Infrared thermometerSep 27, 2022
153 days to decisionK221211 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k221211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Apr 27, 2022
Decision date	Sep 27, 2022
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Shenzhen Yolanda Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Baihua Han
510(k) history	3 submissions · 3 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.
Contact	Reanny Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221211/> 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 26, 2026