

K212598 iHealth infrared Ear thermometer PT5Jan 28, 2022
165 days to decisionK212598 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k212598/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Aug 16, 2021
Decision date	Jan 28, 2022
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Andon Health Co, Ltd.
Location	Tiajin, CN
Contact	Liu Yi
510(k) history	92 submissions · 92 cleared · 2008-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212598/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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