

K210118 INFRARED BODY THERMOMETER (Model: YK-001)Sep 15, 2021
239 days to decisionK210118 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k210118/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Jan 19, 2021
Decision date	Sep 15, 2021
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Longnan Renzhong Medical Equipment Co., Ltd.
Location	Ganzhou, CN
Contact	Liangping Liao
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Sgs-Cstc Standards Technical Services Co., Ltd.
Contact	Iris Fung

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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