

K210014 Infrared Forehead Thermometer (Model: T80, T81, T82, T83, T84, T85)Jun 4, 2021
151 days to decisionK210014 · Product code: FLL · General Hospital
Source: <https://www.510kdatabase.net/k210014/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Jan 4, 2021
Decision date	Jun 4, 2021
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guandong Genial Technology Co., Limited
Location	Zhaoqing, CN
Contact	Jun Yu
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Guangzhou Kinda Biology 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

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