

K202591 Body Infrared Thermometer HT-820DMar 9, 2021
182 days to decisionK202591 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k202591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Sep 8, 2020
Decision date	Mar 9, 2021
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dongguan Xintai Instrument Co., Ltd.
Location	Dongguan, CN
Contact	Wei Wang
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

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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