

**K200159 Non-contact Infrared Body Thermometer,
model:HTD8823US**Jan 5, 2021
349 days to decisionK200159 · Product code: FLL · General Hospital
Source: <https://www.510kdatabase.net/k200159/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Jan 22, 2020
Decision date	Jan 5, 2021
Days to decision	349 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hetaida Technology Co., Ltd.
Location	Dongguan, CN
Contact	Tom Chen
510(k) history	8 submissions · 8 cleared · 2018-2025

REGULATORY CONSULTANT

Consulting firm	Qimmiq Medical Consulting Service Co., Ltd.
Contact	You Yijie

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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