

**K200781 Infrared Body Thermometer**Dec 9, 2020  
273 days to decisionK200781 · Product code: **FLL** · General Hospital  
Source: <https://www.510kdatabase.net/k200781/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Mar 11, 2020
Decision date	Dec 9, 2020
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Heitaida Technology Co., Ltd.</b>
Location	Dongguan City, CN
Contact	Tom Chen
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Qimmiq Medical Consulting Service Co., Ltd.</b>
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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