

K211583 Infrared Thermometer, Model: HW-1Sep 3, 2021
102 days to decisionK211583 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k211583/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	May 24, 2021
Decision date	Sep 3, 2021
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Dongguan Simzo Electronic Technology Co., Ltd.
Location	Dongguan, CN
Contact	Jinlong Wang
510(k) history	3 submissions · 3 cleared · 2018-2023

REGULATORY CONSULTANT

Consulting firm	Shenzhen Reanny Medical Devices Management Consulting Co.,
Contact	Reanny 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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