

**K223807 Reusable Temperature Probe, Disposable
Temperature Probe**Aug 25, 2023
248 days to decisionK223807 · Product code: FLL · General Hospital
Source: <https://www.510kdatabase.net/k223807/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Dec 20, 2022
Decision date	Aug 25, 2023
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Sino-K Medical Technology Co.,Ltd
Location	Baoan District, Shenzhen, CN
Contact	Lao Chengxin
510(k) history	3 submissions · 3 cleared · 2020-2023

REGULATORY CONSULTANT

Consulting firm	Shenzhen Chonconn Medical Consulting Co., Ltd.
Contact	Kevin Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223807/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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