

K240109 Medical electronic thermometer (FC01, FC02)Apr 12, 2024
87 days to decisionK240109 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k240109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Jan 16, 2024
Decision date	Apr 12, 2024
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhuzhou Goldenhot Medical Technology Co., Ltd.
Location	Zhuzhou, CN
Contact	Xianwu Liu
510(k) history	3 submissions · 3 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	Feiyang Drug & Medical Consulting Technical Service Group
Contact	Meihua Cai

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240109/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026