

K230889 Digital ThermometerApr 3, 2024
369 days to decisionK230889 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k230889/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Mar 31, 2023
Decision date	Apr 3, 2024
Days to decision	369 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Wenzhou Yosun Medical Technology Co.,Ltd
Location	Wenzhou, CN
Contact	Lihao Yang
510(k) history	3 submissions · 3 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.
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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230889/> 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 13, 2026