

K232678 Digital Thermometer, Model T28, T28LJan 31, 2024
152 days to decisionK232678 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k232678/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Sep 1, 2023
Decision date	Jan 31, 2024
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Guangdong Genial Technology Co., Ltd.
Location	Zhaoqing, CN
Contact	Yu Jun
510(k) history	5 submissions · 5 cleared · 2023-2024

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/k232678/> 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