

K220276 Infrared Thermometer TET-351Feb 17, 2023
382 days to decisionK220276 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k220276/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Jan 31, 2022
Decision date	Feb 17, 2023
Days to decision	382 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Truly Instrument Limited
Location	Shanwei City, Guangdong, CN
Contact	LiuJin Ting
510(k) history	5 submissions · 5 cleared · 2008-2023

REGULATORY CONSULTANT

Consulting firm	Chonconn Medical Device 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](https://accessdata.fda.gov)

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