

K201508 Infrared ThermometerMar 9, 2021
277 days to decisionK201508 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k201508/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Jun 5, 2020
Decision date	Mar 9, 2021
Days to decision	277 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dongguan Prestige Sporting Goods Co., Ltd.
Location	Taichung, TW
Contact	Zhang Zhao
510(k) history	11 submissions · 11 cleared · 2013-2021

REGULATORY CONSULTANT

Consulting firm	Guangzhou GLOMED Biological Technology Co., Ltd.
Contact	Cassie Lee

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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