

K190984 Infrared Forehead ThermometerApr 22, 2020
373 days to decisionK190984 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k190984/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Apr 15, 2019
Decision date	Apr 22, 2020
Days to decision	373 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xiamen Ants Bro Technology Co., Ltd.
Location	Xiamen, CN
Contact	Jane Xu
510(k) history	3 submissions · 3 cleared · 2019-2020

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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