

K190717 Infrared Thermometer, model: PC808Dec 13, 2019
268 days to decisionK190717 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k190717/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Mar 20, 2019
Decision date	Dec 13, 2019
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Shenzhen Pacom Medical Instruments Co., Ltd.
Location	Shenzhen, CN
Contact	Xuwen Chen
510(k) history	2 submissions · 2 cleared · 2018-2019

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)

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